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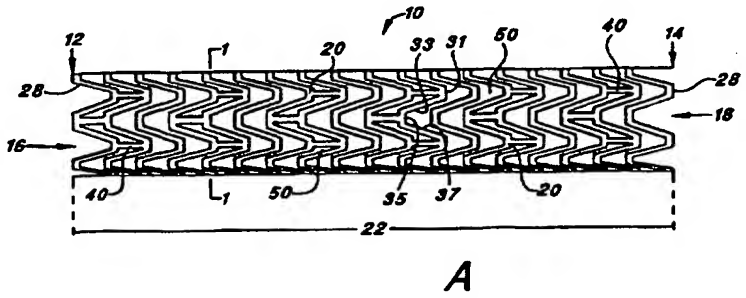
(54) Title: PROGRAMMABLE VARIABLY FLEXIBLE MODULAR STENTS

(57) Abstract

A programmable, variably flexible modular stent includes: (a) a plurality of basic circular ring units (28) made from a thin malleable material, where each basic ring unit has a recurring sequence of circumferential segments (31, 35) and circumferential/longitudinal segments (33, 37); and (b) at least one bridging link (40) that longitudinally connects a circumferential segment of each basic ring unit to a corresponding circumferential segment of an adjacent basic ring unit. The basic ring units which are connected to each other by way of the bridging link(s) thereby form a tubular-shaped stent frame (20). The tubular-shaped stent frame assumes a pre-expanded size (Fig. 3-b) having a first diameter (d1) when the circumferential/longitudinal segments (33, 37) of the basic ring units are oriented to lie predominantly in a longitudinal direction. The tubular-shaped frame assumes an expanded size (Fig. 3-A) having a second diameter (d2) when the circumferential/longitudinal segments of the basic ring units are bent to lie predominantly in a circumferential direction. Advantageously, the second diameter of the tubular-shaped frame may be two to three times greater than the first diameter. Hence, the stent frame (20), when in its pre-expanded size, may be readily inserted into a lumen, and once inserted, may be expanded to assume its expanded size, thereby providing an expanded stent frame which thereafter serves as a supporting structure, i.e., a scaffold, to hold the lumen open with an open diameter that is equal to the second diameter (d2). The rigidity, strength, density, length and flexibility of the stent may be programmably set by selective formation of modules (70, 72), of two or more rings, having prescribed characteristics as determined in large part by selected intra-connections between the rings (28), and by selective inter-connecting the modules or rings with differing patterns of bridging links.



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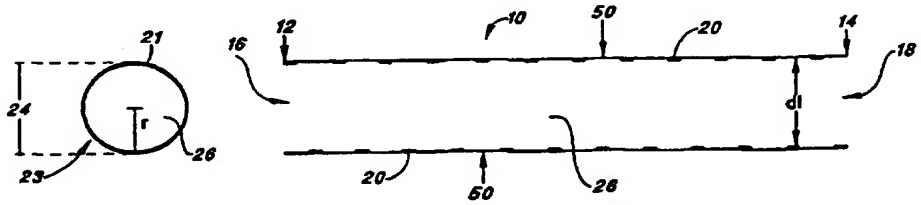

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PROGRAMMABLE VARIABLY FLEXIBLE MODULAR STENTS

The present invention relates to intravascular stents suited for implantation and deployment within blood vessels, ducts, tracts, or other channels within the human body, and more particularly to a modular stent that may be programmed to have varying degrees of flexibility, strength and size.

Background of the Invention

Angioplasty, either coronary or general vascular, has advanced in recent years to be the most effective means of re-vascularization, and has become an alternative to conventional bypass graft surgery. First becoming a practical tool in early 1980's for clinical practice in the coronary artery, the balloon catheter-dependent angioplasty has consistently proven to be the most reliable and practical interventional procedure. Other ancillary technologies, such as lasers or directional or rotational atherectomies, have proven to be either of limited effectiveness or to be dependent on balloon angioplasty to complete the intended procedure.

The restenosis phenomenon following balloon-based angioplasty has been the most obvious drawback of the procedure, especially in the coronary artery system. Many different regimens designed to combat the restenosis phenomenon have not been very successful, including the use of lasers, or a directional or rotational atherectomy. However, in recent years, intravascular stenting has shown noticeable reduction of the restenosis rate following the angioplasty procedures. The intravascular stent depends on the balloon angioplasty for pre-dilatation, stent deployment and post-stent dilatation.

The intravascular stent works like scaffolding erected inside the lumen of a vessel when the vessel is pre-dilated with a balloon, and the stent is properly deployed inside the vessel. The scaffolding effect of the stent advantageously: (a) prevents the common elastic recoil of the vessel wall which has been dilated with the balloon catheter, (b) eliminates the residual stenosis that is commonly seen after completion of a balloon angioplasty, (c) permits the stented vessel segment to maintain a slightly wider vessel lumen than the native unobstructed vessel segments proximal to and distal to the stented segment, and (d) provides a lower restenosis rate for the stented vessel. During the follow up period after angioplasty, the restenosis rate of a stented vessel is significantly lower than any other means used in angioplasty, including the use of drugs or the other technologies mentioned earlier.

There are other benefits of vessel stenting. A good example, specifically in the coronary artery, is the potential reduction of the emergency bypass surgery arising from angioplasty procedures. Stenting has proven to be effective in some cases of impending closure of the vessel during angioplasty; thus, circumventing emergency bypass surgery.

Stenting may also be used to control and stabilize an unstable local intimal tear of a vessel caused by carrying out a normal angioplasty procedure. Moreover, in some cases, an incomplete or less than optimal dilatation of a vessel lesion with balloon angioplasty can successfully be opened up with stent implant.

While in the early days of stenting practice, especially stenting in the coronary arteries, there appeared to be a wide-swinging anti-coagulation problem, better and easier to use regimens developed in recent years for use with the stenting practice have significantly minimized this problem. As a result, the hospital stay following stenting is getting shorter, and outpatient anticoagulation techniques are becoming simpler.

Some representative examples of stents known in the art are found in United States Patent Nos. 5,102,417; 5,330,500; 5,449,373; 5,354,308; 5,545,211; 5,562,697 and 5,569,295. Even more examples of stents may be found in the comprehensive list of prior art patents and references cited, e.g., in the 5,569,295 patent.

Although the stents described or referenced in the above-mentioned U.S. Patents are very effective and beneficial once they are properly deployed and implanted, many have proven very difficult to use due to: (a) columnar rigidity of the un-expanded stent and lack of flexibility to navigate through the corners of the guiding catheter as well as the corners of the native vessels (which generally have tendencies to be tortuous), and (b) flimsiness of the un-expanded stent frame, which may be damaged or distorted during delivery to the vessel lesion site because of the tortuosity and resistance caused by the guiding catheter and the native vessel. Some of the other drawbacks of the current generation stents are: (1) a significant fore-shortening of the stent when the stent is expanded and deployed, and (2) limitations of the stent length due to inherent limitations of the stent design. The lack of flexibility of a stent during the delivery phase of the stent implantation procedure is especially problematic. When the stent is longer in length, the difficulty of using the stent is compounded.

What is needed in the design of future generation stents, and that which is provided by the present invention, is a stent design that allows making the (pre-expansion) stent flexible for easy delivery, while making it structurally strong and free of distortion to the stent frame after deployment, as well as providing the capacity to allow longer stents. Advantageously, the new stent of the present invention is designed to be more flexible for easy delivery; while retaining the desired structural soundness and endurance

when deployed. Furthermore, the design of the new stent of the present invention may be programmed during its manufacture so that it is variably flexible, having a selected or set stent frame density; and further so that a wide variety of structural stent modules can be formed that allow the overall stent length to be readily selected. These advantageous key features of the stent invention described herein should set new standards for all future coronary and vascular stent designs.

Summary of the Invention

The above and other features and advantages of the present invention are provided in a stent that comprises a thin walled metal frame in a cylindrical shape designed to be implanted inside a vessel wall by means of delivery via a catheter-based delivery vehicle. The stent, in a pre-expansion form, assumes a relatively low profile during delivery, but is readily transformed into an expanded high profile form when deployed. The expanded stent opens the inside lumen of a target segment of a vessel (or a duct) by expansion of the stent frame from inside so that the lumen created through the expanded stent is about the same as the original native vessel lumen size or slightly larger. Once the stent is properly delivered and deployed, it is generally left implanted permanently, i.e., it is not removed.

The stent of the present invention has the expandability provision built into its structural design, thereby allowing the stent frame to expand to a designed size, and thereby realizing the desired effect of the stent--to hold open the lumen of the vessel in which it has been deployed. Because the stent must expand, and because once expanded it must have very thin walls (else the lumen opening would be blocked) yet exhibit sufficient frame strength to prevent collapse, the stent is made from a thin, strong, malleable material such as metal or wire. However, it is to be noted that any new material, including polymers, could be used in the future for the stent material providing such material meets the essential structural and expandability requirements of the stent design described herein.

Various techniques and methods may be used to expand the stent once it is delivered inside the target lesion of a vessel. These techniques and methods include: (a) self-expansion by the metal memory of the stent frame when released from trapping means, (b) balloon mounted stents that would be passively expanded into place by inflation of the delivery balloon, (c) a combination of the two methods (a) and (b) mentioned above, or (d) any other method yet to be developed or discovered. Advantageously, the stent of the present invention is not limited to a particular expansion technique or method, but any of the above methods or techniques may be used.

It is a feature of the present invention to provide a new stent design which overcomes the negative characteristics and drawbacks commonly found in prior art stents available in the market today. For example, many of the currently available stents are structurally flimsy and lack sufficient scaffolding strength against the resistant or recoiling forces commonly encountered within a vessel where the stent is deployed. Others of the currently-available stents, while providing enough structural strength to withstand the vessel resistance or recoil, are very rigid and non-flexible, making it very difficult for such stents to track the generally tortuous and sometimes resistant natural vessel within which they are introduced. Still other prior art stents work well once delivered and deployed properly, but are very difficult to deliver to the vessel because the stent in its pre-expansion mode is too stiff and inflexible for negotiating the naturally tortuous vessels. Additionally, some prior art stents have a tendency to foreshorten their length when deployed and expanded. Such foreshortening is a negative feature that has its origin in a flawed stent frame design.

The new stents of present invention overcome the above and other negative characteristics , while at the same time maximally enhancing the desirable features of a viable stent design, by providing a programmable, variably flexible and modular stent comprised of (symmetrical) *alternating trapezoidal cycle rings*. Such alternating trapezoidal cycle rings form the *basic ring units* of the stents of the present invention. As will be evident from the description that follows, these basic ring units comprise a circular ring without any break made from trapezoidal shaped cycles that permit circumferential expansion. A completed stent made in accordance with the present invention is made up of multiple basic ring units arranged into a tubular shaped *stent frame*, wherein each of the individual basic ring units of trapezoidal cycles are interconnected by *the bridging links*. These bridging links are specially designed so that the stent frame is not distorted or foreshortened when the stent is circumferentially expanded. The inter-connection distance of the bridging links that connect the basic ring units does not change before and after expansion of the stent. This specially designed bridging link distance of the basic stent ring units is designated herein as the *equi-distance*.

As will be seen in the illustrations of the stent shown hereafter in the figures, the stent of present invention overcomes the deficiencies of the first-generation (prior art) stents by providing a stent design that allows flexibility and programmability. By "programmability", it is meant the ability to easily set design parameters during the manufacture, forming, or assembly of the stent that impart to the stent a set of desired performance characteristics (e.g., rigidity, density, flexibility, length, etc.).

Advantageously, the stent of present invention offers the following novel features which enhance its performance: (1) the stent matrix is programmable to meet the specific clinical applications; *programmability* , as that term is used herein, is an entirely new concept to stent design; (2) the individual basic trapezoidal cycle rings may be *unitized* into *modular units* within a stent, i.e., a single stent may be made up of several modular stent units, each of which has its own set of characteristics (which may be the same as or different from the characteristics of other modular units within the stent), or the entire stent may comprise a single module; (3) the necessary *rigidity* and strength of the stent can be *tapered* or *variably set* in certain locations within the stent by selective programming of the *frame density* and the *bridging link* placements; (4) the stent frame can likewise be programmed to have variable flexibility for easy delivery; and (5) foreshortening of the stent (in any length) when the stent is expanded is negligible .

One embodiment of the invention may be characterized as a programmable, variably flexible modular stent that includes: (a) a plurality of basic ring units made from a thin-walled malleable material, where each basic ring unit has a recurring sequence of circumferential segments and circumferential/longitudinal segments; and (b) at least one bridging link that longitudinally connects a circumferential segment of each basic ring unit to a corresponding circumferential segment of an adjacent basic ring unit. The basic ring units connected to each other with the bridging link(s) thereby form a tubular-shaped stent frame. The tubular-shaped stent frame assumes a pre-expanded size having a first diameter when the circumferential/longitudinal segments of the basic ring units are oriented to lie predominantly in a longitudinal direction. The tubular-shaped frame assumes an expanded size having a second diameter when the circumferential/longitudinal segments of the basic ring units are bent to lie predominantly in a circumferential direction. Advantageously, the second diameter of the tubular-shaped frame may be two to three times greater than the first diameter. Hence, the stent frame, when in its pre-expanded size, may be readily inserted into the lumen of a vessel having a diameter greater than the first diameter. Once inserted into a desired location of the lumen, the stent frame may then be expanded to assume its expanded size, thereby providing an expanded stent frame which thereafter serves as a supporting structure, i.e., a scaffold, to hold the lumen open with an open diameter that is equal to the second diameter.

Another embodiment of the invention may be viewed as an improved intravascular stent for implantation and deployment within the lumen of a vessel, wherein the sent has a pre-enlarged diameter which facilitates its insertion into the lumen of the vessel, and wherein once so inserted means are provided for expanding its diameter to an enlarged diameter which supports and holds open the lumen. Such , improved intravascular stent

is characterized by: (a) a multiplicity of basic circular ring units of alternating trapezoidal cycles arranged and connected to form a tubular frame; and (b) at least one bridging link that connects each of the basic circular ring units to an adjoining basic circular ring unit, wherein the number, length, and circumferential location of the bridging link(s) is programmed to set the flexibility/rigidity and density/strength of the stent.

Yet another embodiment of the invention may be characterized as a method of making an intravascular stent. Such method includes the steps of: (a) cutting a prescribed stent pattern out of a small diameter and thin-walled metal tube by: (1) forming and arranging a multiplicity of basic circular ring units of alternating trapezoidal cycles to form a tubular frame, (2) connecting at least one bridging link between each of the basic circular ring units and an adjoining basic circular ring unit, and (3) programming the number, length, and circumferential location or pattern of the bridging link(s) to set the flexibility/rigidity and density/strength of the stent.

In summary, the present invention advantageously uses combinations of varied bridging link patterns between individual basic ring units, as well as the variably programmable density setting of the individual basic ring units in a stent matrix, to provide stents which are truly modular and variably flexible in any length. Further, the modularity feature of the invention, i.e., being able to assemble smaller modular units to make a larger stent unit, or being able to break down a larger prefabricated stent unit into a smaller stint module, just before implanting the stent in a patient, truly provides an implant physician with a flexible and versatile stent not heretofore known. It is believed that the novel stent features of present invention will thus set a new benchmark standard for all future generations of intravascular stents.

Brief Description of Figures

The above and other aspects, features and advantages of the present invention will be more apparent from the following description, presented in conjunction with the following drawings, wherein:

FIG. 1-A is a side elevation of the generally cylindrical and tubular shape of a stent made in accordance with the present invention;

FIG. 1-B is a longitudinal section of the cylindrically shaped stent of FIG. 1-A;

FIG. 1-C is a cross-sectional view taken across the line 1-1 of FIG. 1-A;

FIG. 2-A illustrates an isolated basic ring unit used as a basic building block for the stent of the present invention, which ring unit comprises an alternating trapezoidal cycle;

FIG. 2-B shows an "opened-flat" pattern of a programmable variably flexible modular stent formed using a plurality of ring units of the type shown in FIG. 2-A, joined using three bridging links in a loosely spiral spatial inter-connecting link pattern, with an open sector of 300 degrees;

FIG. 3-A shows the open geometry of one half of the circumference (i.e., 180 degrees) of a stent made in accordance with the present invention when the stent is circumferentially expanded;

FIG. 3-B shows the pre-expanded geometric pattern of the stent of FIG. 3-A;

FIGS. 4-A through 4-D respectively show four variations of the alternating trapezoidal cycle stent rings of the present invention;

FIGS. 5-A and 5-B show the length ratio of "h" and "v" of the trapezoidal cycle stent rings needed to achieve a desired circumferential expansion;

FIGS. 6-A through 6-M show variations of the bridging link connections, which bridging link connections may be used between individual basic ring units, between a module and individual basic rings units, or between modules;

FIG. 7 shows a variation of a bridging link pattern between individual basic ring units, and is an example of a unitized two ring module with low frame density;

FIG. 8 shows an example of a unitized three-ring module having medium frame density;

FIG. 9 shows an example of a unitized four-ring module having a high frame density;

FIG. 10 shows an example of an "un-connected" arrangement of the basic ring units which provides a medium frame density by stacking the individual ring units in a medium overlap pattern, wherein the individual basic ring units are evenly spaced through out the entire length of the stent frame, and wherein the stent is ready for "programming" of the bridging links;

FIG. 11 illustrates an example of a programmed stent that uses four bridging links between each basic ring unit uniformly, wherein the spatial interconnecting pattern is loosely spiral, and wherein open sectors in the inter-space between individual ring units range from about 150 to 90 degrees, thereby providing a stent pattern which is borderline between a totally unitized modular pattern and a medium-to-low flexibility interconnected individual ring units;

FIG. 12 depicts an example of a totally unitized stent wherein the entire stent is a single module with little flexibility and high rigidity, and further wherein three interconnected spines pass through the entire stent length, with a total of five bridging links being used between the individual basic ring units;

FIG. 13 shows another example of a totally unitized stent wherein the entire stent is a single module with high rigidity and no flexibility, with six interconnecting spines passing through the entire stent length, and with a total of seven bridging links being used between the individual basic ring units;

FIG. 14 illustrates an example of using programmed modular units inside of a stent having a frame density that is uniform with medium density, and wherein single rings are inserted between modules to impart a desired flexibility; with two single rings being placed on each end for progressive flexibility, and wherein only two bridging links are used for inter-modular and inter-basic ring connections for flexibility, and further wherein the spatial inter-connecting pattern is loosely spiral;

FIGS. 15-A, 15-B and 15-C illustrate variations of stent frame density to achieve, respectively, a high frame density, a medium frame density, and a low frame density, where frame density affects the rigidity and strength of the stent when deployed;

FIG. 16 shows an example of a variable frame density that is programmed so that the frame density progressively increases towards the center of the frame;

FIG. 17 illustrates a the use of two-ring modules in a partially programmed stent, wherein among six two-ring modules, four modules use twelve intra-modular bridging links paced at the center, and two modules use four intra-modular links placed at the periphery, and further wherein single unconnected ring units (not yet programmed) are used between modules, and two unconnected single ring units are placed on both ends of the stint;

FIG. 18 depicts further programming of the stent of FIG. 17, wherein the single ring units placed between the modules and the twin single ring units placed on both ends of the stent are shown as being interconnected by two bridging links connecting two consecutive peak-to-peak or valley-to-valley equi-distances, and wherein the inter-connecting link mode is loosely spiral, thereby providing a stent that has a very rigid and strong frame in its center section, yet remains flexible during deployment;

FIG. 19 shows an example of a stent programmed in accordance with the present invention to have a strong frame density in the center of the stent, while maintaining overall good flexibility, wherein the stent of FIG. 19 has eight two-ring unitized modules which are directly inter-connected by two consecutive peak-to-valley or valley-to-peak equi-distances, and wherein the twin single ring units on both ends of the stent are also interconnected to the stent by two inter-connecting links;

FIG. 20 shows another example of a stent similar to FIG. 19, except that single ring units are placed on each end of the stent rather than two;

FIG. 21 depicts a further modification of the stent of FIG. 20, wherein the single ring units have been removed from the ends of the stent, thereby providing a stent wherein the central core of the stent is not altered, but wherein the stent is now symmetrically shorter without compromising the stent flexibility;

FIG. 22 shows further symmetrical shortening of the stent of FIG. 21, wherein six two-ring modules are used at the center of the stent, and single ring units are placed on each end of the stent;

FIG. 23 illustrates one way in which the stent of FIG. 19 may be programmed to be asymmetrically shortened, wherein one single ring unit and one two-ring module have been removed from the left end of the stent, thereby providing a stent frame the strong center core has effectively been shifted to the left, and the tapered flexibility is conversely shifted to the right, thus illustrating the type of stent programming that may be used to allow the stent to be designed to fit a specific vessel condition in clinical practice;

FIG. 24 depicts a further variation of the stent of FIG. 23, wherein the single-ring end piece on the left in FIG. 23 has been removed, thereby making the stent one ring shorter and further shifting the center core section further to the left; and maintaining a progressive flexibility and tapered rigidity in the right end of the stent;

FIG. 25 shows yet an additional variation of the stent of FIG. 24, thereby further illustrating the versatile programmability of the stent, wherein the left end of the stent now comprises a medium density two-ring module having twelve intra-modular links achieved by removing a 6-link unitized two-ring module from the left end of the stent of FIG. 24, thereby shifting the high density and high strength core to the left half of the stent, while providing a low density and very flexible portion on the right half of the stent; and

FIG. 26 shows still a further variation of the stent of FIG. 24, wherein the two single basic rings have been eliminated from the right end of the stent, thereby providing a stent which has all two-ring modules of varying frame density and intra-modular links.

Corresponding reference characters indicate corresponding components throughout the several views of the drawings.

Detailed Description of the Invention

The following description is of the best mode presently contemplated for carrying out the invention. This description is not to be taken in a limiting sense, but is made merely for the purpose of describing the general principles of the invention. The scope of the invention should be determined with reference to the claims.

As an overview, the present invention provides a programmable, variably flexible and modular stent comprised of *alternating trapezoidal cycle rings*. Such alternating

trapezoidal cycle rings form the *basic ring units* of the stents of the present invention. It should be noted that the term "trapezoidal", as used herein, describes not a trapezoid, but rather refers to the type of bends, or wiggles, or zig-zags, that occur in the structure of each of the basic ring units. That is, as will be evident from the description that follows, and with momentary reference to FIGS. 5-A and 5-B, each basic ring unit 28 comprises a circular ring without any break made from a recurring sequence of four segments. A first segment 31 of the basic ring unit traverses a first circumferential path that is parallel to the central axis of expansion 36. A second segment 33 traverses a path that is both circumferential and longitudinal (where longitudinal refers to the longitudinal axis of the tubular-shaped stent). A third segment 35 of the ring unit traverses a second circumference path, also parallel to the axis of expansion 36, while a fourth segment 37 of the ring unit traverses a path that is both circumferential and longitudinal. This cycle repeats around the entire circumference of the ring. Because the first and third segments 31 and 35 of the ring traverse paths that are circumferential, such paths are effectively parallel to each other. In contrast, the paths traversed by the second and fourth segments 33 and 37 of the ring are not parallel to each other. A side view of the ring thereby has a trapezoidal appearance, with two recurring segments 31, 35 traversing paths that are essentially parallel to each other, and two other recurring segments 33, 37, traversing paths that are not parallel to each other. The ring thus has the appearance of an alternating trapezoidal cycle, with the non-parallel segments of the ring providing the means for permitting circumferential expansion of the ring as the non-parallel segments 33 and 37 are bent to become more circumferential and less longitudinal.

A completed stent made in accordance with the present invention is made up of multiple basic ring units 28 arranged into a tubular shaped *stent frame* 20 (FIG. 1-A), wherein each of the individual basic ring units of trapezoidal cycles are interconnected by *the bridging links* 40. These bridging links are specially designed so that the stent frame is not distorted or foreshortened when the stent is circumferentially expanded. The inter-connection distance of the bridging links that connect the basic ring units does not change before and after expansion of the stent. This specially designed bridging link distance of the basic stent ring units is designated herein as the *equi-distance*.

As is evident from the illustrations of the stent shown in the figures, the stent of present invention provides a stent design that allows a high degree of flexibility and programmability. Not only is the stent matrix programmable to meet the needs of a specific clinical application, but the individual basic trapezoidal cycle rings may be unitized into modular units within a stent. By programming the individual modules so that each

has its own set of characteristics, and then combining the modules within a single stent, the stent may be formed to have a desired rigidity and strength.

The new stents of present invention may be made of a metal, a polymer or a combination thereof. For easily understanding the description of the invention which follows, the stents will be described as being made of a metal. However, it is to be emphasized that a metal represents only one example of the type of material which may be used. If metal is used, a stainless medical grade steel or its alloy, a non-steel metal such as titanium or its alloy, tantalum-based alloys, or any other suitable metal may be used to make the stents described herein.

A significant advantage of the new stents of the present invention is that they may be manufactured or formed by any of a number of different approaches. One effective fabrication method of making the pre-expansion stent frame is to cut the stent frame pattern out of a small diameter and thin-walled metal tube using laser etching or other precision etching techniques known in the art, such as EDM (Electron Discharge Machining). Making the stent frame out of a metal tube in this fashion is very desirable because the end product has no seams or welded points.

Another technique for making the new stents of the present invention is to make them out of a thin flat sheet metal. The frame pattern of the stent is first cut from the flat sheet with a laser, EDM or other industry-wide practiced cutting method. Then, the flat stent pattern is rolled into a tubular form and the appositive ends of the pattern at the seam are welded or bonded together using laser or electrical welding techniques or any other suitable bonding process. Theoretically, the stent of present invention may also be made using a metal molding technology.

Similarly, it should be noted that the same stent design can be made using metal wires. When metal wires are used, the basic stent ring unit is fabricated with metal wire and then the inter-modular and intra-modular bridging joints are welded to join the basic ring units together to form the desired modular units and/or completed stent. While using wires in this manner could be more cumbersome and increase the cost of fabrication as compared to using the other methods using thin-walled metal tubes or sheets mentioned above, there may be some specific advantages or purposes offered by a stent made of metal wire over the stents formed from thin metal tubes or sheets.

The preferred wall thickness of the stent frame of present invention, if made of stainless steel or its alloy, is between about 0.002 inches (0.051 mm) to about 0.020 inches (0.508 mm) if the vessel size is less than about 4.0 mm in luminal diameter. If the vessel size is larger, the thickness of the stent frame should also be enlarged proportionally as needed. The preferred width of the trapezoidal cycle ring of the stent frame of the

present invention, if made of stainless steel or its alloys, is between about 0.005 inches (0.127 mm) to about 0.100 inches (2.54 mm), if the vessel size is 4.0 mm or less in diameter. If the vessel is larger, the frame width of the stent of present invention should be adjusted accordingly. If the stent of present invention is made of stainless steel wire, the frame dimension (i.e.- frame width and wall thickness) would generally be influenced by the diameter of the metal wire from which the stent is made. For a vessel less than about 4.0 mm in diameter, the diameter of the wire could be as small as about 0.004 inches (0.102 mm) to as large as about 0.020 inches (0.508 mm).

As indicated above, the stent of the present invention is made of specially designed basic circular ring units of alternating trapezoidal cycles. A completed stent has a set (or programmed) number of these individual basic ring units arranged and connected in a tubular fashion, resulting in a cylindrical stent form. The individual basic ring units are connected together using the uniquely designed bridging links. This basic circular ring units have the alternating trapezoidal curve cycles illustrated in the figures of this application.

The alternating trapezoidal curve cycles of the individual basic ring units are designed for the following purposes: (a) to allow the stent to achieve two to three times expansion or more of the stent diameter when expanded and deployed in a vessel (transforming from the low pre-expansion profile) -- this is an essential requirement because the stent must be delivered into a vessel in a very low profile over a stent delivery vehicle catheter, but must also be able to be expanded to a large enough profile to provide the scaffolding effect of a fully open vessel lumen, which may be *2 to 4* times as large as the diameter of the delivery profile of the stent; and (b) the spacing between individual basic ring units is variably set for variable frame density control -- for example, the individual basic ring units may be arranged loosely with free space between the basic units or they may be arranged closely stacked, overlapping the alternating trapezoidal curves of the individual basic ring units. When the basic ring units are stacked closely to form a completed stent, the frame density of the stent is increased and, therefor, the scaffolding strength of the stent is also increased once deployed in a vessel. However, if a stent has a uniform high frame density setting throughout its entire length, such stent may be strong but may also be too rigid and inflexible for delivery to the target vessel. The frame density of the stent of the present invention may advantageously be set to different values within the same stent in order to incorporate into the stent variable flexibility and variably tapered rigidity characteristics. That is, within the same stent, certain segments (or modules made from one or more of the basic ring units) can have a stronger and tighter frame pattern, while other segments (or modules) may have looser and more flexible frame patterns. Thus, selected variations and/or combinations of the frame density and the bridging link

pattern may be used to create the desired strength and flexibility characteristics needed for the particular stent application, thereby imparting to the stent characteristics and capabilities that go far beyond the capabilities of stents currently available in the market.

Another advantageous feature of the invention is that the number and location of *bridging links* ,which are inserted between the individual basic ring units to couple or join such basic ring units together, may be widely varied. That is, some adjacent basic ring units may be joined together using a single bridging link located at just one point on the circumference of the ring unit; while others of the ring units may be joined using patterns of two, three, four, or more bridging links located at various locations around the circumference of the ring unit. The most common and preferred bridging link patterns are fully disclosed and described in connection with the figures of this application described hereafter.

The number of bridging links and the link pattern determine the modularity, rigidity and flexibility of the end product. For building or programming modules (i.e. sub-units) within a stent, the bridging links are generally placed evenly for balanced frame strength or rigidity. The number of bridging links within a module determines the cage strength or rigidity of the module; the higher the number of bridging links, the higher the cage strength. Furthermore, different modules within the same stent may be programmed as needed to exhibit desired flexibility, rigidity and strength, according to the clinical application criteria.

All of the interconnections made within the stent using the bridging links, i.e., the interconnecting of the basic ring units to form modules, and the interconnecting of modules and/or basic ring units to form a completed stint, may be programmed differently from an intra-modular link program. Generally, interconnecting is done in such a way that the flexibility of the whole stent is maximized while the integrity and stent strength are well maintained. The interconnecting patterns of the bridging links may be many and varied as the figures of this application illustrate. The interconnecting bridging links are typically confined to a sector of the stent circumference that is less than about 180 degrees in order to maximize the flexibility characteristics of the whole stent. The spatial pattern of the inter-connecting bridging links along the stent column is preferably that of a loosely wound spiral, rather than a straight line, in order to effect a maximum torsion flex of the pre-expanded stent during the delivery phase of the stent procedure.

The *modular design* of the stent of the present invention provides far-reaching implications. Such modularity not only permits programming the modular characteristics within a given pre-fabricated stent, but it also facilitates the concept of breaking down (i.e.- separating) a longer pre-fabricated stent into smaller modular units, as well as joining smaller pre-fabricated modular units into a larger stent unit, just before using or implanting

the stent in a patient. Such modular stent product thus offers a highly customized stent capable of meeting the specific needs of the individual patient in whom the stent is to be implanted. Moreover, this concept of making smaller stent units out of a larger (i.e.- longer) unit, or the reverse concept of making a larger stent unit by putting together (i.e.- joining together) smaller modular units of different rigidity and varying flexibility (and with different density setting), may advantageously be used during product development; thereby affording clinical operators (i.e.- physicians) the opportunity to select, process and use the modular stent product of the present invention in the operating room when they are doing the stent implant procedure on patients. This ability of (easily) selecting or programming the right combination of the desired stent features (through application and selection of particular modular units) in the operating room as the stent implant procedure is being carried out represents a significant and important feature provided by the modular stent concept of present invention -- a feature which, to applicant's knowledge, is not known or present in prior art stent designs.

Next, the invention will be described with reference to the figures. As an aid in keeping track of the various components shown in the figures, Table 1, below, provides a list of each reference character and the corresponding component identified by such reference character.

TABLE 1

List of Character References Used in Figures

Ref. No.	Description
10	- Stent of the alternating symmetrical trapezoidal cycle rings
11	- Frame pattern of the open stent
12	- Proximal end of stent
14	- Distal end of stent
16	- Proximal opening

Table 1 (cont)

Ref. No.	Description
18	- Distal opening
20	- Stent frame
21	- Wall thickness of stent frame
22	- Length of stent
23	- Circumference of stent
24	- Diameter of stent
26	- Stent lumen
28	- Basic ring unit of alternating (symmetrical) trapezoidal cycle; Pre-expansion mode
30	- Joining point of the basic ring unit, where break was made to illustrate open stent pattern
32	- Peak of alternating (symmetrical) trapezoidal cycle of the basic ring unit
34	- Valley of alternating (symmetrical) trapezoidal cycle of the basic ring unit
36	- The central axis of expansion of the basic ring unit of alternating (symmetrical) trapezoidal cycle
31, 35	- Parallel segments of the basic ring 28 that follow a circumferential path
33, 37	- Non-parallel segments of the basic ring 28 that follow paths that include both circumferential and longitudinal components
38	- Dimension of open circumference
40	- Bridging link of the valley-to-peak equi-distance between the basic ring units of alternating trapezoidal cycle
41	- Un-connected equi-distance of valley-to-peak
42	- Bridging link of the peak-to-valley equi-distance between the basic ring units of alternating trapezoidal cycle
43	- Un-connected equi-distance of peak-to-valley
44	- Un-connected equi-distance between the basic ring units
46	- Inter-connecting link space
48	- Intra-modular link space
50	- Open space between the stent frame structures
52	- Open frame pattern of the expanded stent; one half of full circumference
54	- Open frame pattern of the pre-expansion stent; one half of full circumference
56	- Spine of bridging links in the stent
57	- Symmetrical alternating trapezoidal cycle ring
58	- Asymmetrical alternating trapezoidal cycle ring
60	- Pointed peak alternating trapezoidal cycle ring
62	- Rounded peak alternating trapezoidal cycle ring
64	- Dotted box defining the circumferential spread (vertical length) and the columnar spread (horizontal length) of an open trapezoidal cycle of the basic ring unit

Table 1 (cont)

Ref. No.	Description
66	- Vertical length (i.e.- circumferential spread)of trapezoid of the basic ring unit
68	- Horizontal length (i.e.- columnar spread) of trapezoid of the basic ring unit
70	- Two ring unitized module
72	- Three ring unitized module
74	- Four ring unitized module
76	- Multi-ring (more than four rings) unitized module
78	- High (relatively) density spacing
80	- Medium (relatively) density spacing
82	- Low (relatively) density spacing
84	- Parameter Box
86	- Longitudinal axis of the stent frame 20

Turning then to FIGS. 1-A, 1-B and 1-C, a stent 10 made from alternating trapezoidal cycle rings 28 in its usual cylindrical shape in a pre-expansion mode is schematically illustrated. The side elevation of the stent 10 is shown in FIG. 1-A, while a longitudinal cross-section of the same stent 10, showing the stent frame in a linear arrangement, is depicted in FIG. 1-B, and a lateral cross-section of the stent is represented in FIG. 1-C. The stent 10 is a cylindrical shaped metal object with the frame pattern 20 as illustrated. As indicated, the side elevation of FIG. 1-A is in the pre-expansion mode, where the frame has a diameter of d1. The trapezoidal pattern, arranged vertically in the view of FIG. 1-A, gives expansion of the individual trapezoidal rings 28 by stretching the alternating trapezoidal segments 33 and 37 or cycles.

When expanded, the stent 10 assumes a larger diameter and profile, having a diameter d2 (as seen best in FIG. 3-A). Because the purpose of a stent is to scaffold the inner lumen of a vessel or duct in the patient's living body, but must be delivered in a low profile mode into a vessel, the stent is designed to begin in a low profile condition of the pre-expansion mode for delivery into a vessel by a form of a catheter. When it is deployed in the vessel the frame of the stent expands to an extent so that the stent can scaffold the inner lumen of a vessel to its fullest dimension. This necessity of dual modes of the stent profile is a special requirement in designing an effective stent for the human blood vessels. A stent that can perform well in a blood vessel can also be effectively adopted for utilization in the non-blood-vessel organ systems in the body, such as in: bile duct, esophagus, trachea, ureter, urethra and so forth, by changing the dimensions to meet the needs of application.

Still with reference to FIGS. 1-A, 1-B and 1-C, the stent 10 of present invention has a proximal end 12 and a distal end 14, with a specific length 22 between the two ends.

There is proximal opening 16 at the proximal end and distal opening 18 at the distal end. The longitudinal section (FIG. 1-B) shows the inner lumen 26 of the stent 10 with the thin walled stent frame 20 in a tubular arrangement. The proximal opening 16 and the distal opening 18 connect with the stent lumen 26. The cross section (FIG. 1-C), taken across the line 1-1 of the side elevation (FIG. 1-A) shows the circular cross sectional shape with a diameter 24 (also shown as d1), radius r (where 2r=d1), very thin wall thickness 21 and a circumference 23.

There are considerable open spaces 50 within the stent frame 20. This open space 50 becomes larger when the stent is deployed in a vessel and is expanded. A balance must be struck between the total surface area of the stent frame and the open space between the stent frame. This is because, on the one hand, the total surface area of the stent 10 should be maximized in order to provide maximum scaffolding structural integrity to the stent. On the other hand, however, the total surface area should be minimized so as to minimize the foreign body effects of the stent frame, which foreign body effects can invite intra-luminal clotting of blood inside the stent 10 when it is deployed inside a blood vessel. Another reason for having open spaces 50 within the stent frame 20 is that if the stent is going to expand, a frame pattern must be made that allows room for the structure of the expanded frame to lie in the plane of the non-expanded frame. Thus, the open spaces 50 provide room for the non-parallel segments of the basic circular rings 28 to lie when the frame is in its non-expanded mode.

FIGS. 2-A and 2-B illustrate a stent frame pattern that is opened and spread flat, where the ordinarily cylindrical or tubular shaped object consists of the alternating trapezoidal cycle rings 28. The basic individual rings 28 of the alternating trapezoidal cycle are interconnected to each other by bridging links 40 using a specific bridging link pattern. FIG. 1-A illustrates an isolated basic ring unit 28 of the alternating trapezoidal cycle. The vertical length of the open basic ring 28 is the circumference of the stent when it is in its ordinarily cylindrical shape in the pre-expansion mode.

FIG. 2-B illustrates the open stent frame pattern 11. Although the stent, as used, is a cylindrical object, for the purpose of illustration, the frame pattern of the stent 10 of present invention is shown in the two dimensional flat open sheet. As seen in FIG. 2-b, the stent 10 has an integral frame with a given length 22 (see FIG. 1-A) and the circumferential dimension 23 in cylindrical shape. The stent length 22 (in horizontal dimension) is same in FIG. 1-A as it is in the open stent matrix of FIG. 2-B, but the circumferential dimension (in vertical dimension) is 38 in the open stent 11 of FIG. 2-B, and is 23 in the cylindrical stent 10 of FIG. 1-C. Both 23 and 38 indicate the same circumferential dimension, depending on the form of illustration.

The stent 10 of present invention comprises a number of basic ring units 28, aligned concentrically about a longitudinal axis 86. One of the basic ring units 28 is shown in FIG. 2-A, which is cut open flat at the break point 30. As has been indicated previously, this primary ring unit 28 is made up of alternating trapezoidal cycles of symmetrical geometry, i.e., parallel segments 31 and 35, and non-parallel segments 33 and 37. The metal ring unit 28 has a very thin wall thickness 21 (as seen best in FIG. 1-C) and has a certain width that makes the stent frame 20. For the design shown in FIG. 2-A, there are six alternating trapezoidal cycles with peaks 32 and valleys 34 in each ring unit 28. In the open stent frame pattern 11 of FIG. 2-B, it is seen that there are 17 of these basic ring units 28 arranged horizontally with even equi-distances 44 between the individual basic ring 28 units. In order to make the individual ring 28 units into an integral stent frame 11, the bridging links are used that connect the equi-distance of peak-to-valley 42 and the equi-distance of valley-to-peak 40. These bridging links are programmable in length, number and pattern. The linking mode of the bridging links used in the stent pattern 11 of FIG. 2-B has a loosely spiral shape, spiraling around the longitudinal axis 86 of the stent. In other words, the link pattern is not in straight line but spirals over the circumferential surface of the cylinder of the stent 10. For the pattern 11 of FIG. 2-B, there are three bridging links that join adjacent individual rings 28. Two consecutive valley-to-peak bridging links 40 have one peak-to-valley link 42 sandwiched therebetween. In this way, the space between two consecutive basic rings 28 serves as an inter-connecting link space 46.

When the stent is delivered into a vessel and deployed, the stent has to expand in diameter 24 and circumference 23 & 38. The whole stent frame of FIG. 2-B expands like a single basic ring 28 expands. In FIG. 2-A, a dotted line 36 runs through the middle of the ring circumference 38. This dotted line 36 is the central axis of expansion of the trapezoidal cycle ring 28. As this alternating trapezoidal cycle ring is expanded and straightened, the circumference 23 & 38 increases in dimension making the diameter 24 of the stent 10 change from d1 to a new expanded diameter d2 (see FIG. 3-A). As the non-parallel segments 33 and 37 of trapezoidal cycle of the basic ring 28 straighten, the valleys 34 and peaks 32 move toward the central axis of expansion 36.

Exactly the same phenomenon of expansion occurs when the entire stent frame 11 is expanded in its cylindrical stent form 10. That is, the seventeen individual ring units 28 of the stent frame 11 expand exactly in the same fashion as the single basic ring unit 28 shown in figure 2-A expands. When all the individual ring units are expanded, e.g., as occurs in the real stent deployment in vivo, the connected equi-distances of the bridging links 40 & 42, as well as the un-connected equi-distances 41 & 43, do not change. This

is the reason why these distances are called "*equi-distance*" for purposes of this invention, and this is also why the bridging links in the equi-distances 44 prevent any distortion of the stent frame 11 during expansion of the stent 10 when it is placed in a vessel in vivo.

Although the example of FIG. 2-B shows seventeen (n=17) basic ring units 28 in the open stent 11, it is to be understood that the length 22 of the stent 11 can be made longer by adding more basic ring units 28 to the stent 11, or be made shorter by reducing the number of ring units 28 to make the stent 11 shorter. (The length of the stent 11 can also be changed, as explained more fully below, by changing the equi-distance spacing between adjacent rings, thereby increasing or decreasing the ring density.) Thus, the stent 10 can be made as short as 5 mm or as long as 5 cm or even longer by simply adding or reducing the number of the basic ring units (28), or by changing the spacing between adjacent basic ring units. The stent 10 of present invention does not have any inherent structural limitations with regards to the stent length it can have. Any necessary stent length 22 can be programmed and constructed as the clinical needs dictate.

The versatile determination of the length 22 of the stent 10 of present invention is made possible due to the ingenious bridging link (40 & 42) concept of the equi-distances (44) between individual ring units (28). Because the equi-distance 44 between individual ring units 28 does not change before and after expansion of the stent 10, and also does not change regardless of the frame density setting as will be seen later, there is a great deal of freedom and ease of making the stent 10 in any desired length. Furthermore, using this equi-distance 44 for bridging links of 40 & 42 offers an enormous variety of inter-connecting choices and patterns between the individual ring units 28. All of the equi-distances can be used for bridging links 40 & 42, or only a selected number of equi-distances 44 can be inter-connected by programming the bridging link inter-connections.

Advantageously, the ability to program the number and pattern of bridging links that are used to realize the inter-connections of the equi-distance 44 between the individual ring units 28 offers a unique and ingenious method of making the entire stent 10 or part of the stent 10 modular. This ability to program the entire stent 10 or part of the stent 10 and make it modular provides new approaches and opportunities for making better and advanced next-generation stents.

FIGS. 3-A and 3-B depict the post-expansion mode (FIG. 3-A) and the pre-expansion mode (FIG. 3-B) of the open stent frame patterns. These figures thus illustrate how the stent 10 expands when it is deployed inside a vessel and when caused to expand. FIG. 3-A shows how the stent frame is transformed (52) by expansion from the pre-expansion frame 54 of FIG. 3-B. The expanded frame 52 shows how the individual basic

ring units 28 expand in circumferential dimension 38 through the straightening of the alternating trapezoidal cycles, i.e., the non-parallel segments 33 and 37, of the basic ring unit 28. The expanded frame 52 in FIG. 3-A still shows some residual alternating trapezoidal curves (i.e., the segments 33 and 37 are not completely straight), indicating that there is some residual circumferential length that can be further straightened for additional circumferential length 38 of the individual ring units (28). Note that both the expanded frame 52 and un-expanded frame 54 show only one half (1/2) of the full circumference 38 of the basic ring unit 28 (which ring has six alternating trapezoidal cycles, only three of which are visible in FIGS. 3-A and 3-B).

As is evident from FIGS. 3-A and 3-B, the equi-distances 44 , the bridging links 40 & 42, and a spine 56 of bridging links has not changed between the un-expanded frame 54 and expanded frame 52. The total area of open space 50 within stent frame 20 has increased when the pre-expansion frame 54 is expanded. The (vertically) parallel arrangement of the individual ring units 28 has not changed, however, between the pre-expansion frame 54 and the post-expansion frame 52. In fact, each individual ring unit 28 in the stent is individually expanded by straightening its own alternating trapezoidal cycles without interfering with other individual basic ring units; even though all of the ring units are inter-connected by a certain varying (programmable) number of bridging links 40 or 42. Because the stent 10 is made by adding certain numbers of the individual basic ring units 28, without changing the equi-distances 44 between individual ring units 28, before and after expansion of the stent 10, the total length 22 of the stent 11 is literally unchanged in the post-expansion 52 frame. Any minute amount of shortening of the stent length 22 is caused by less than half of the horizontal width of the individual ring unit 28 of alternating trapezoidal cycles, located at each end 12 & 14 of the stent 10. This is because when the individual basic ring unit 28 expands, it elongates along its own central axis of expansion 36, as shown in FIG. 2-A. Only less than half of the horizontal spread of the individual basic ring unit 28 at either end (12 & 14) of the stent 11 would be lost. Therefore, the total reduction of the stent length 22 (due to stent expansion) would be less than the horizontal width of the a single basic ring unit 28 regardless of the total length 22 of the basic ring units 28 in the stent 11. The proportional reduction of the length 22 of the stent 10 of present invention becomes less and less as the number of basic ring units 28 used in the stent 10 is increased.

Turning next to FIGS. 4-A through 4-D, representative examples of variations of the alternating trapezoidal cycle patterns that may be used in the variably flexible modular stents of the present invention are illustrated. These variations include symmetrical alternating trapezoidal cycles (FIG. 4-A), asymmetrical alternating trapezoidal cycles

(FIG./ 4-B), pointed peak alternating trapezoidal cycles (FIG. 4-C), and the rounded peak alternating trapezoidal cycles (FIG. 4-D). It is to be understood that these and other variations are contemplated as falling within the scope of present invention, although separate extended illustrations are not made for each of the variations included in FIGS. 4-B, 4-C, and 4-D. For simplicity, the illustrations in this application is based on the (symmetrical) alternating trapezoidal cycle ring 57 of FIG. 4-A.

FIG. 4-A is most representative of the alternating trapezoidal cycles of the basic ring unit 28 of present invention. However, the same programming principles can be applied to any of the variations shown in FIGS. 4-B, 4-C and 4-D, or other variations not shown in the drawings. FIG. 4-A illustrates the symmetrical alternating trapezoidal cycles 57. Potential bridging link points 41 and 43 are shown (with dotted lines) to illustrate the potential equi-distance 44 of peak-to-valley and valley-to-peak spaces when more than one basic ring unit 28 is arranged in lengthwise direction to form a stent. FIG. 4-B is an example of asymmetrical alternating trapezoidal cycles 58 in contrast to the symmetrical alternating trapezoidal cycles 57 of FIG. 4-A. FIG. 4-B has potential bridging link points 41 & 43. Any peaks or valleys of the alternating trapezoidal cycle have the potential bridging link points 43 and 41, respectively. FIG. 4-C illustrates pointed peak alternating trapezoidal cycles 60. Note that the pointed peak alternating trapezoidal cycle 60 also has the same potential bridging link point of 41 and 43. FIG. 4-D illustrates a rounded peak alternating trapezoidal cycle 62. The basic ring unit 28' of the cycle 62 could also be used like any of the other trapezoidal cycle rings 57, 58 & 60. The rounded peak ring cycles 62 also have the potential equi-distance bridging points of 41 & 43.

FIG. 5-B shows an enlarged view of one unit of the alternating trapezoidal cycle defined by a dotted line box 64 (FIG. 5-A). The length ratio between the dimensions (v) and (h) ultimately determine the maximum expansion rate of the pre-expanded stent. That is, the dotted box 64 of FIG. 5-A defines the dimensions of a single cycle of the basic ring 28 of the alternating trapezoidal cycles 57. As can be seen in FIG. 5-B, the single trapezoidal cycle in the dotted box 64 has a circumferential spread 66 (i.e.- vertical or circumferential length) and a columnar spread 68 (i.e.- horizontal or longitudinal length). The ratio of circumferential spread 66 to the columnar spread 68 determines the expansion rate of the basic ring unit 28. Because expanded stent must be large enough to support the fully open stented vessel lumen, while maintaining low pre-expanded profile for easy delivery into the vessel via a carrier stent vehicle based on an angioplasty catheter, pre-determining the maximum expandable rate of the stent is very important at the programming and construction stage of a stent product made in accordance with the present invention.

The columnar spread 68 (i.e.- horizontal or longitudinal length) of the trapezoidal shaped ring represents the potential expandable length when the basic ring 28 is fully expanded. The circumferential spread 66 (i.e.- vertical or circumferential length) is already used up to make up the circumference 38 of the un-expanded stent size, therefore it does not contribute to the potential circumferential expansion of the trapezoidal shaped ring defined in the dotted box 64.

If the ratio of the columnar spread 68 to the circumferential spread 66 is one to one (1:1), then the expanded circumference may become twice (2x) as large as the un-expanded circumference 38. This is because the columnar spread 68 straightens vertically toward the central expansion axis 36 when the basic ring unit 28 is expanded, making the alternating trapezoid cycle 57 into a straightened mode 52 of the basic ring unit 28 as shown in FIG. 3-A. Likewise, if the columnar spread 68 is twice as large (2x) as the circumferential spread 66, the potential expanded circumference of the basic ring unit 28 becomes three times (3x) as large as the un-expanded circumference 38. Similarly, if the columnar spread is three times (3x) as large as the circumferential spread, then the expanded circumference becomes four times (4x) as large as the pre-expansion circumference 38.

Therefore, in view of the above design constraints, an understanding of the ratio between diameter and circumference of a circle is important, because when the cylinder-like stent 10 is used clinically, it is the diameter of the stent or the diameter of the vessel used as the sizing reference.

As is well known from simple geometry, the relationship of the circumference to diameter is expressed by formula:

$c = 2\pi r$ where: c is circumference and
r is the radius (or ½ diameter)

Thus, it is seen that

$d = c/\pi$ where: d is diameter (or 2r)

Therefore, the ratio of the circumference to diameter is one to one (1:1). Based on this ratio, if the circumference is to increase two times (2x) as large, the diameter must also enlarge by two times (2x). Similarly, if the circumference is to increase by three times (3x), the diameter must similarly increase by three times (3x), and so forth. Therefore, during the programming and construction stage of the stent 10 of present invention, the diameter of the expanded stent can be predicted by the potential circumferential expansion rate of the individual basic ring unit 28, based on the principles discussed above.

Turning next to FIGS. 6-A through 6-M, there are shown various illustrations of the specifically designed bridging link patterns that may be used between two individual

basic ring units 28 in accordance with the present invention. Each bridging link connects the equi-distance between apposing peaks 32 and valleys 34 of the two adjacent basic ring units 28. This equi-distance remains the same when the stent is expanded because the central axis of expansion 36 of the alternating trapezoidal cycle is at the center of the basic trapezoidal ring, as illustrated in FIG. 2-A.

FIG. 6-A shows a single bridging link 40 between the two basic ring units 28, inter-connecting the valley-to-peak equi-distance. This single bridging link could be a link connecting the equi-distance of peak-to-valley 44 space just as well. The whole space between these two basic ring 28 units may be called an inter-connecting link space 46. This inter connecting link space partially contributes to the open space 50 of the stent frame 20 in the stent 10.

FIG. 6-B uses two consecutive valley-to-peak 40 or peak-to-valley 42 equi-distance bridging links between two basic ring 28 units. Two consecutive valley-to-peak 40 or peak-to-valley 42 bridging links can be programmed for the same purpose. FIG. 6-C illustrates a bridging link pattern connecting three consecutive equi-distances between the two basic ring 28 units as shown. Alternatively, the reverse pattern could also be used, i.e., linking two consecutive peak-to-valley 42 links and sandwiching the valley-to-peak 40 link in between. FIG. 6-D shows three bridging links utilizing two consecutive valley-to-peak links 40 and one peak-to-valley link 42 immediately adjacent to the two link combination. A reverse arrangement would give the same effect: two consecutive peak-to-valley links 42 and one valley-to-peak link 40 at a immediately adjacent location.

FIG. 6-E shows a cluster of four bridging links connecting four consecutive peak-to-valley and valley-to-peak equi-distances. FIG. 6-F illustrates two sets of double bridging links separated by 120 degrees from each other. FIG. 6-G has a cluster of five bridging links, achieved by adding one more bridging link to the link pattern of FIG. 6-F. Another variation (not shown) would be to link all four equi-distances between the two bridging links set in a 165 degrees arc.

FIG. 6-H has two bridging links placed 180 degrees from each other. FIG. 6-I shows a variation of the link pattern of FIG. 6-H realized by adding another bridging link in the middle between the two links set 180 degrees apart. FIG. 6-J shows yet another variation in which two bridging links are added inside the 180 degree arc of the primary links placed 180 degrees apart (i.e.- FIG. 6-H) making a total four bridging links, with two adjacent links set apart inside the arc. FIG. 6-K illustrates three separate pairs (i.e.-doubles) of bridging links set apart 120 degrees from each other. The unconnected equi-distances between the three pairs of double links are even. FIG. 6-L is an example of connecting six alternating equi-distances out of twelve total equi-distances. As seen in

FIG. 6-L, the connected and un-connected equi-distances are evenly programmed. Finally, FIG. 6-M shows three separate triple cluster links evenly placed 120 degrees apart. There are three (n=3) un-connected equi-distances between the triple bridging link clusters separating them from each other. Finally, all the equi-distances between the two basic ring units 28 may be connected, as illustrated below in FIG. 7.

Among all the variations of bridging link patterns illustrated in FIGS. 6-A through 6-M, some are better suited for the role of inter-connecting links, some are better suited for intra-modular links, and still others fall in an in-between category. The bridging link patterns illustrated in FIGS. 6-A, 6-B, 6-C, 6-D and 6-E are good examples of inter-connecting links that provide the needed flexibility of the pre-expansion stent 10 during the delivery phase of the stent procedure. In contrast, the bridging link patterns shown in FIGS. 6-J, 6-K, 6-L, 6-M and 7 are progressively better suited for intra-modular linking to unitize the individual basic ring 28 units that are formed into a unitized module. The bridging links shown in FIGS. 6-F, 6-G, 6-H and 6-I fall in the in between category that could be used either as an inter-connecting link or as an intra-modular unitizing link, depending on the specific purpose and programming of the stent to be constructed.

The distinction between the inter-connecting links and intra-modular links should be clear, First, the inter-connecting links are designed to impart a desired flexibility into the stent during the delivery phase of the stent procedure; realized by inter-connecting an individual ring unit 28 to another basic ring unit, inter-connecting two unitized modules, or inter-connecting an individual basic ring 28 unit to a unitized module. The inter-connecting links perform their flexible interconnecting function best when the arc or circumferential sector wherein the inter-connecting links are placed is less than 180 degrees, or even better when the arc or sector is less than 120 degrees. The key factor for inter-connecting links is to provide the necessary stent flexibility while maintaining the integrity of the total stent. With the programmable ability of the stent of present invention, the flexibility may be variably set to meet the needs of the particular application at hand.

Second, the intra-modular links are designed to unitize the individual basic ring 28 units into a relatively solid module utilizing two, three, four or more individual basic ring 28 units, as necessary. The intra-modular links perform their function best when the unitizing links are placed evenly around the full circumference. This requirement of intra-modular links is just the opposite of the inter-connecting link requirement. The more intra-modular links that are used the more solid and rigid the module becomes.

FIG. 7 shows the formation of a module with two parallel alternating trapezoidal cycle ring units. The particular link pattern shown in FIG. 7 has 12 bridging links between

the two basic ring units to form a unitized module 70. As a result, the module 70 is unitized as a highly rigid single unit. Note that the frame density is relatively low with no "overlap" between adjacent basic ring units 28. Because the maximum number of bridging links are used to unitize the 2-ring module, the 2-ring module 70 is solid and behaves as a single unit. The inter-space between the two unitized basic ring units 28 is called an intra-modular link space 48. The intra-modular link space 48 becomes the open space 50 between the stent frame 20, just like the inter-connecting link space 46 (FIGS. 6-A through 6-I) becomes. The frame density setting of the module 70 is relatively low because the two ring units 28 that make up the module 70 are not as close together as they could be.

FIG. 8 shows the formation of a module 72 having three parallel, evenly-spaced, alternating trapezoidal cycle ring units 28 which are unitized by the bridging links between them. This module 72 has a moderately rigid frame structure. The frame density of module 72 is characterized as medium with some "overlap" between the frames. By "overlap", it is meant that the peak on one ring unit encroaches into the valley of an adjacent ring unit. For overlap to exist, the length of the bridging links 40 and 42 used within the module 72 must be shortened relative to the length of the bridging links used in the module 70 of FIG. 7.

Note that the intra-modular link pattern used within the module 72 is similar to the inter-connecting bridging pattern shown in FIG. 6-K. However, it is to be emphasized that FIG. 8 is only one example. Any suitable inter-connecting link pattern illustrated, e.g., in the examples of FIGS. 6-A through 6-M could be used, especially the link patterns of FIGS. 6-J, 6-K, 6-L or 6-M or the inter-connecting pattern illustrated in FIG. 7. As discussed earlier, the more intra-modular links which are used to unitize the module, the higher the rigidity of the module. The frame density setting of the module 72 is characterized as medium, having a slightly higher frame density than exists for the module 70 of FIG. 7. Therefor, the intra-modular link space 48 within the module 72 is slightly narrower in this example than that shown for the module 70 of FIG. 7.

FIG. 9 illustrates the formation of a module 74 having four parallel alternating trapezoidal cycle ring units 28 that are closely packed with maximum overlap, being unitized by the short bridging links between them. The frame density of module 74 is thus high, although the rigidity of a stent frame made using this module is about the same as would be achieved with module 72 (FIG. 8). This is because the intra-modular link pattern of the module 74, which pattern determines in large part the rigidity, is similar to that of module 72. However, as evident from FIG. 9, the frame density of the four ring module 74 is higher than that of the modules 70 or 72 shown in FIGS. 7 and 8.

As previously mentioned relative to FIG. 8, any of the inter-connecting patterns illustrated in FIGS. 6-J, 6-K, 6-L, 6-M or in FIG. 7 could be used within the module 74 of FIG. 9. The higher the number of inter-connecting bridging links that are used in unitizing the basic ring units 28 in a module, the higher the rigidity and strength but the less the flexibility. If a module is not too long, regardless of its rigidity, it can still function as a flexible sub-unit in a completed stent by using a flexible inter-connecting link pattern to an adjacent sub-unit, i.e., to an adjacent single ring unit 28 or to an adjacent module.

Note that the same techniques used to form the unitizing module 74 may be used to make a multi-ring module having more than four individual ring units. The unitized module concept may be applied to a short module that is to function as a sub-unit in a complete stent, or the entire stent may be unitized into rigid module, if necessary, by selective programming of the inter-connecting links and/or intra-modular links.

Turning next to FIG. 10, an illustration is shown to define terms and to demonstrate the programmability of the stent construction in an opened and flat stent matrix. More particulary, FIG. 10 illustrates how the basic alternating trapezoidal cycle ring units 28 can be arranged in any length, and/or in any frame density to meet the needs and requirements of the particular clinical application in which the stent is to be used. Shown in FIG. 10 are twenty five (n=25) six cycle basic ring units 28 which are evenly spaced at a medium frame density in a columnar fashion, but which are not yet connected by any bridging links. Thus, FIG. 10 shows an example of a partially programmed stent, i.e., a stent that includes frame density programming, but wherein no programming of the bridging links between the individual ring units 28 has yet occurred. The un-connected equi-distances 44 between the individual ring units 28 are clearly evident. The break points 30 of the individual basic ring (28) unit are also clearly illustrated in this open stent arrangement. In order to make a stent out of the flat matrix frame shown in FIG. 10, programming of the inter-connecting links is necessary. Such programming of the inter-connecting links and intra-modular links imparts specific characteristics to the stent which finally results.

Next, with reference to FIG. 11, an example is presented of how the partially programmed stent ring 28 arrangement of FIG. 10 can be transformed into a definitive stent by programming the inter-connecting links. In FIG. 11, there are seventeen individual basic ring units 28 evenly spaced along the columnar spread (i.e.- horizontally) at a medium frame density. In each of the inter-connecting link spaces 46 a distinctive set of four (n=4) bridging links is used throughout the entire stent. The same inter-connecting pattern repeats every third inter-connecting space. The bridging link pattern employs two consecutive peak-to-valley 42 (or valley-to-peak 40 links) with a third

valley-to-peak 40 (or peak-to-valley 42 link) sandwiched in between them. A fourth link is then placed at the peak-to-valley 43 (or valley-to-peak 41) equi-distance that is 180 degrees from the first inter-connecting link. This inter-connecting pattern repeats in each of the inter-connecting spaces 46, but with the starting point of bridging links in the adjacent inter-connecting space 46 being off-set in such a way that the bridging link pattern, when viewed in a cylindrical stent formed by connecting the edges 30 together to form a cylinder, would have the appearance of a spiral which spirals around the longitudinal axis of the cylindrical stent. Thus, this bridging link pattern may be characterized as having a more or less a loosely spiral mode as it propagates longitudinally (horizontally as shown in the figures) along the spatial wall of the stent frame 20.

Note that in the pattern shown in FIG. 11, an aberration of the inter-connecting link pattern is found at the inter-connecting link spaces (starting from left to right) of the 3rd, 9th and 15th columns. That is, except for the 3rd, 9th and 15th inter-connecting link spaces, there are open sectors of 150 & 90 degrees in each inter-space. However, any such aberrations are not problematic as there is no requirement that a precise, aberration-free pattern be used. One of the advantages of the present invention is that almost any bridging link pattern may be used, so long as the desired rigidity/flexibility, and density/strength requirements are met.

The stent of FIG. 11 is not quite a definite modular form. The stent pattern used in FIG. 11 interconnects the individual basic ring units 28 throughout the entire stent using a bridge link pattern that follows a loosely spiral mode . The stent shown in FIG. 11 has a medium to medium-low flexibility, and a medium rigidity and frame strength. These characteristics are evenly distributed through out the entire stent 11.

Referring next to FIG. 12, an example is shown of how the entire stent may be made into a unitized module, exhibiting little flexibility and high rigidity, by programming the bridging link pattern shown. Compared to the stent frame used in FIG. 11, the stent frame of FIG. 12 has no flexibility. The entire FIG. 12 stent, in cylindrical form, would behave like a rigid cage when deployed in a vessel.

As seen in FIG. 12, five bridging links are used in each of the intra-modular link spaces 48 in certain repeating patterns through out the entire stent 11. This particular form of bridging link pattern programming produces three (n=3) spines 56 of bridging links running the entire length 22 of the stent 11, separated by 90 degrees from each other around the circumference of the stent.

With the bridging link programming producing the spatially-separated spines 56 shown in FIG. 12, the resulting stent becomes a single unitized rigid module made of seventeen individual basic ring units 28. The inter spaces between the basic ring units

becomes the intra-modular link space 48. There is thus no inter-connecting link space 46 in the stent shown in FIG. 12. The presence of such inter-connecting link space 46, as exists in the patterns shown in others of the figures, signifies a more flexible inter-connection between modules, between basic ring units or between a basic ring unit and a module.

FIG. 13 further illustrates the programming versatility of the stent 10 of present invention. The stent frame 11 shown in FIG. 13 produces a stent that is more rigid than the stent frame seen in FIG. 12. This is because the stent frame 11 in FIG. 13 now has six (n=6) spines 56 running the entire length 22 of the stent frame 11; produced by programming a bridging link pattern which includes seven bridging links placed in the particular equi-distances between the individual basic ring units 28. Because the entire stent frame 11 shown in FIG. 13 is a single rigid module, the link space between the basic ring units 28 becomes the intra-modular link space 48.

The stent 11 of FIG. 13 would exhibit no flexibility during delivery to the vessel, but would result in a very strong cage-like scaffolding effect when deployed in the vessel. Through programming of the bridging link pattern, one could add up to six more spines 56 to the stent frame 11 of FIG. 13, thereby placing a maximum of twelve (n=12) spines 56 in the stent frame 11. A twelve-spine stent frame (n=12) would produce a stent that would be even more rigid than the stent frame 11 shown in FIG. 13.

FIG. 14 shows an example of a programmed modular stent pattern, using fifteen evenly spaced basic ring units 28. The first two basic ring units, number one and two (from left to right), are solo basic ring units, while number three and four are unitized into a 2-ring module 70. The number five, six and seven basic ring units 28 are unitized into 3-ring modules 72 using six bridging links in every other equi-distance space between the individual basic ring units. The three (n=3) 3-ring unitized modules 72, located in the center of the stent, are separated from each other by solo basic ring units 28. A 2-ring module 70 is placed next to the third 3-ring module (72), and this is followed by two solo ring units 28 located at the right end of the stent frame 11 of FIG. 14.

FIG. 14 also includes a vertical box 84 on the right hand side. The box 84 is considered an integral part of the figure because the programming complexity of the sophisticated stent concept shown in FIG. 14 (as well as many of the other figures presented herein) is too difficult to fully understand and appreciate from a simple examination of the stent frame shown in FIG. 14. Thus, for any figure in which a box 84 appears, such box 84 presents and interprets the complex specifications of the programmed stent frame 11 appearing to its left . Box 84 is referred to hereafter as the

parameter box 84. An example of how to read the information contained within the parameter box 84 is presented in the following paragraphs.

RIGIDITY of the stent frame 11 shown in FIG. 14 is moderate at the center, with three (n=3) 3-ring modules 72 located at the center, each being unitized by six intra-modular links 42 bridging the equi-distances 44 in the intra-modular link spaces 48. These 3-ring unitized modules 72 themselves are moderately rigid, but the stent frame 11 remains quite flexible because the three ring modules 72 are arranged symmetrically with single ring units 28 sandwiched between them. At the periphery on each side, there are 2-ring modules 70 unitized by six peak-to-valley links 42 in the intra-modular link spaces, similar to the 3-ring modules 72. There are also solo rings 28 inserted between the two ring modules 70 and the three ring modules 72. On both ends of the stent frame 11, a pair of solo basic ring units 28 are placed bilaterally. With such programming of the rigidity characteristics, the stent 11 exhibits the necessary rigidity at the center of the stent for strength, but with very little loss of flexibility. The rigidity is symmetrically tapered from the center toward both ends (12 & 14) of the stent frame 11, where rigidity is low.

FLEXIBILITY of the stent frame 11 of FIG. 14 is somewhere between high to medium, while maintaining a very good rigidity in the center by the three-ring modules 72 and two-ring unitized modules 70. The flexibility of this stent frame of FIG. 14 is characterized as being symmetrically progressive from the relatively rigid center toward the highly flexible ends. Although there are three (n=3) 3-ring unitized modules 72 at the center, the flexibility of the center portion of the stent 11 is very little compromised due following factors: (a) although the 3-ring modules 72 are inherently rigid, the columnar length of the modules 72 is relatively short; (b) single basic ring units 28 between modules 70 and 72 act as flexibility buffer; (c) the inter-connecting spaces 46 between the solo ring unit 28 and the modules 70 and 72 are inter-connected by two (n=2) bridging links 40 or 42 which connect two consecutive valley-to-peak 41 and peak-to-valley 43 equi-distances, creating a 270 degree arc of un-connected space in each of the inter-connecting spaces 46, thereby providing a wide angle flexing capability of the inter-connecting spaces; and (d) two solo ring 28 units on both ends further add a very flexible head and tail of the stent frame 11. The net effect of being able to program flexibility characteristics into the stent frame design is to produce a variably flexible stent in terms of: (a) variable flexibility in different parts of a same stent, and (b) flexibility differences in one stent as compared to another stent.

FRAME DENSITY for the stent frame 11 of FIG. 14 is medium and the spacing of the basic ring units 28 is uniform through out the entire stent frame. The inter-connecting link spaces (46) and the intra-modular link spaces (48) are spaced evenly.

The STENT RING PATTERN for the stent frame 11 of FIG. 14 is symmetrical alternating trapezoidal cycles 57 (See FIG. 4-A). This is the same as the basic ring units 28 described through out in this application. It is understood, however, that other stent ring patterns could just as easily be employed.

The MODULAR PATTERN of the stent frame 11 of FIG. 14 is rather complex. For easy translation of the programmed modular pattern. numbers are used to represent the sequence of the pattern. Thus, the modular pattern shown in FIG. 14 is represented by following numerical sequence: 1, 1, 2, 1, 3, 1, 3, 1, 3, 1, 2, 1, 1. This sequence of numbers is interpreted as follows: (starting from left to right and counting a solo ring unit as a module) - this stent has two solo ring units at the left end 12 of the stent frame, which are followed by a 2-ring module 70, followed by a solo ring 28, followed by a 3-ring module 72, followed by a solo ring 28, followed by a 3-ring module 72, followed by a solo ring 28, followed by a 2-ring module 70, followed by two solo rings. A comma (",") after the module number signifies that an inter-connecting link space 46 exits between the modules.

The INTRA-MODULAR LINKS portion of the parameter box 84 shows a sequence of hyphenated numbers. Each hyphenated number pair refers to the placement modules (not counting the solo ring units) from left to right, and describes the number of rings 28 in each module and the number of intra-modular links in each module. For the stent frame 11 shown in FIG. 14, the sequence of hyphenated numbers corresponding to the intra-modular links is as follows: (2-6, 3-6, 3-6, 3-6, 2-6). This sequence is interpreted as follows: the first hyphenated number pair corresponds to the first module of the stent frame (starting from left to right). Thus, "2-6" means that the first module (not considering solo ring units) in FIG. 14 comprises a 2-ring module 70 unitized with 6-intra modular links. The other hyphenated number pairs in the sequence are similarly interpreted. Thus, the 2-ring module 70 unitized with 6-intra modular links is followed by a 3-ring module 72 unitized with 6-intra modular links, followed by another 3-ring module 72 unitized with 6-intra modular links, followed by yet another 3-ring module 72 unitized with 6-intra modular links, followed by a 2-ring module 70 with 6-intra modular links.

In order to see how these modules are integrated in the total stent frame 11, all one need do is to read the representation of the MODULAR PATTERN in the parameter box 84 as discussed above.

The INTER-CONNECTING LINKS in the parameter box 84 likewise is represented by a numerical sequence, with the individual numbers being separated by commas. The sequence presented is intended to represent how the bridging links are

programmed to connect the equi-distances 44 between modules and between solo rings. That is, "inter-connecting links" refers to the number of bridging links that are placed in the inter-connecting link space 46, but does not refer to the bridging links placed in the intra-modular link spaces 48.

By way of illustration, in FIG. 14, the following sequence is presented in parameter box 84 as the inter-connecting links: (2, 2, 2, 2, 2, 2, 2, 2, 2, 2) or (2x10). This expression or sequence is interpreted as follows: the first "2" corresponds to the first inter-connecting link space 46 (from left to right) and indicates that this link space has 2-bridging links connecting 2-equi-distances 44; the second "2" in the sequence likewise indicates that there are 2-bridging links in the second inter-connecting link space; the third "2" in the sequence indicates that there are also 2-bridging links in the third inter-connecting link space; and so forth; repeating for ten times. In summary, (2x10) indicates there are ten separate 2-bridging links in the stent frame 11 of FIG. 14.

The term INTER-CONNECTING LINK MODE in the parameter box 84 indicates how the inter-connecting link pattern (or mode) relates on the cylindrical spatial surface of the stent frame 10. The phrase or characterization " Loosely Spiral " indicates that the inter-connecting links are not laid in a straight line, but laid in a loosely spiraling pattern on the spatial surface of the cylindrical stent frame. This loosely spiraling link pattern is selected to give even flexibility of the stent 10 in any direction around the circumference 23 of the stent frame and at any point in the tubular length 22 of the stent 10. The flexibility performance of a stent that has a loosely spiral spatial inter-linking mode would be far superior to a stent which has a straight line inter-connecting mode.

STENT LENGTH is self explanatory in that the length expressed in mm or cm indicates the approximate length of the stent programmed and illustrated in the figure.

END PIECE(S) indicates the type of flexibility programming used in each end of the stent frame. Because either solo rings or modules may be used at the proximal end 12 and the distal end 14 of the stent, the "end piece(s)" characterization within the parameter box 84 provides an indication of how the stent will behave when it is delivered inside a vessel. Also, such information provides some indication as to whether or not the end pieces would be traumatic to the vessel wall during the setting or expanding of the stent in the vessel with a high pressure balloon catheter. To some extent, a solo ring piece 28 at the leading and following end of the stent would be more flexible and less traumatic than a multi-ring rigidly unitized module on either end of the stent.

Turning now to FIGS. 15-A, 15-B and 15-C, there are shown examples of the versatile programmability of the frame density of a stent made in accordance with the present invention. Such versatile programmability of the frame density is a feature that

has been sorely lacking from prior art stents in the market. FIG. 15-C shows how a low frame density may be set by programming the number and closeness of the basic ring units 28. As can easily be appreciable, the frame density of FIG. 15-C is relatively low. On the other hand, the frame density shown in FIG. 15-A is relatively high. The frame density shown in FIG. 15-B is medium, somewhere between the densities of FIGS. 15-A and 15-B.

Being able to program frame density variably adds another dimension to the stent design of present invention. The frame density can be variably programmed in different locations of a same stent, or the frame density of different stents can be programmed differently according to the requirements of the particular clinical application at hand. Note that as the frame density decreases, the length of the equi-distances 44-A (FIG. 15-A), 44-B (FIG. 15-B) and 44-C (FIG. 15-C) increases. The higher the density, the shorter the equi-distance; the lower the density, the longer the equi-distance.

FIG. 16 shows an example of a partially programmed stent frame that has a tapering frame density. (Note that FIG. 16, like FIG. 10, is only partially programmed because no inter-connection of the basic ring units 28 using bridging links 40 or 42 is shown.) As evident from FIG. 16, the frame density is symmetrically accelerated toward the center of the stent matrix. That is, there are four (n=4) basic ring units 28 at the center of the stent matrix having a high frame density setting. On each side of these high density basic ring units, there are groups of four (n=4) basic ring units 28 of medium density. At each end of the matrix, there are groups of four (n=4) basic ring units 28 of low frame density. Therefor, there are a total of twenty (n=20) basic ring units 28)in this matrix; with proportionally higher frame density setting from periphery to center. This simple illustration shows how programmability of the frame density can advantageously be used with the present invention.

Still with reference to FIG. 16, the equi-distance 44-A is significantly wider than the equi-distance 44-C, illustrating the inter-connecting distance of the two different frame density settings. The equi-distance 44-B is in between the equi-distances of 44-A and 44-C. The equi-distance does not change when the stent is expanded, regardless of frame density variation. That is, the equi-distance 44A remains the same both before and after expansion, as does the equi-distances 44-B and 44-C, even though these equi-distances are not the same. A convenient mechanism for programming the density setting is to adjust the length of the bridging links that must eventually connect across the equi-distances of adjacent ring units.

. Turning next to FIGS. 17-26, several examples are shown of a programmed stent at various stages of the programming, including representative variations of the

programming. For example, FIG. 17 illustrates a partially completed stage of bridging link programming. The stent matrix used in FIG. 17 is the same, insofar as frame density is concerned, as that shown in FIG. 16 except for the fact that a single solo basic ring 28 has been inserted between the two 2-ring modules 70 of high frame density at the center. Therefor, the stent matrix of FIG. 17 has a total of 21 basic ring units 28, rather than the 20 ring units shown in FIG. 16.

As evident from FIG. 17, there are six (n=6) 2-ring 70 unitized modules in the matrix. Solo basic ring units 28 are placed between these 2-ring modules 70. Although the modules 70 are linked and unitized, the solo ring units 28 are not shown as being linked yet in order to illustrate a programming approach of the bridging links. The parameter box 84 of FIG. 17 defines the partially completed stent of this figure. (For definitions and interpretations of expressions in parameter box 84, reference should be made to the description above presented in connection with FIG. 14.

The RIGIDITY associated with the stent matrix of FIG. 17 is symmetrically tapered from the center of the stent matrix. FLEXIBILITY is progressively increased toward the periphery. However, the stent resulting from the matrix shown in FIG. 17 would be very flexible, including the center, because the 2-ring modules 70 have a very short columnar spread (i.e.- horizontal length), and further because solo basic ring units 28 have been inserted between the 2-ring modules 70 to function as a flexibility buffer. The FRAME DENSITY of the stent matrix of FIG. 17 is accelerated toward the center from both ends symmetrically; thus, high density is achieved in the center of the matrix and low density is achieved in the periphery. The STENT RING PATTERN shown in FIG. 17 is alternating trapezoidal cycles. The MODULAR PATTERN for the stent matrix of FIG. 17 is characterized as (1,1,2,1,2,1,2,1,2,1,2,1,2,1,1). The INTRA-MODULAR LINKS are characterized as (2-4, 2-12, 2-12, 2-12, 2-4). The INTER-CONNECTING LINKS are not yet programmed. The INTER-CONNECTING LINK MODE is similarly not yet programmed. The STENT LENGTH would be in the range of 25-30 mm.

FIG. 18 shows the completed stent programming from the partially programmed stent matrix shown in FIG. 17. The inter-connecting link space 46 and the intra- modular link space 48 are properly marked. Note the differences of three different equi-distances 44-A, 44-B and 44-C. The parameter box 84 defines the completed stent of FIG. 17. (For definitions and interpretations of the information presented in the parameter box 84, reference should be made to FIG. 14 and its accompanying text.)

The RIGIDITY of the stent illustrated in FIG. 18 is tapered from the center symmetrically. FLEXIBILITY of this stent is progressively increased from the center

toward both ends. The overall flexibility of the stent 11 of FIG. 18 should be excellent to very good. FRAME DENSITY is accelerated toward the center; with a high density at the center and a low density at the periphery. The high density segment of the stent would be best suited for the center of a lesion in a vessel, where the highest scaffolding effect of the stent is needed. The STENT RING PATTERN is (symmetrical) alternating trapezoidal cycles (of six cycles). The MODULAR PATTERN is expressed as follows: (1,1,2,1,2,1,2,1,2,1,2,1,2,1,1). The INTRA-MODULAR LINKS are characterized as follows: (2-4,2-12,2-12,2-12,2-12,2-4). Further, the INTER-CONNECTING LINKS are described as: (2,2,2,2,2,2,2,2,2,2,2,2,2,2) or (2x14). The INTER-CONNECTING LINK MODE is loosely spiral on the spatial surface of the stent column. The STENT LENGTH of this design would be very suitable as a stent with 25-30 mm in length. The END PIECES comprise two solo ring units 28 on each end.

Turning next to FIG. 19, yet another programming variation of the stent matrix of Figure 16 is shown. In the stent of FIG. 19, there are eight (n=8) two-ring unitized modules 70 of three different frame densities. No solo basic ring unit 28 is placed between the 2-ring modules 70, but there are two solo ring units 28 on each end of the stent 11. The intra-modular link spaces 48 and inter-connecting link spaces 46 are clearly marked. The parameter box 84 for FIG. 19 defines the features and parameters of the stent.

As seen in the parameter box 84 of FIG. 19, the RIGIDITY of the stent 11 is symmetrically tapered from the center of the stent. FLEXIBILITY of the stent is progressively loosened toward both ends. The overall flexibility of this stent may be slightly less flexible than the stent of Figure 18, mainly because the solo rings 28 are eliminated from the spaces between modules; thus, eliminating the flexible buffer. The FRAME DENSITY of the stent 11 of FIG. 19 is accelerated toward the center of the stent; with a high density at the center, a medium density in the intermediate zones and a low density at the peripheries. the STENT RING PATTERN comprises alternating six trapezoidal cycles. The MODULAR PATTERN is characterized by the following sequence: (1,1,2,2,2,2,2,2,2,2,1,1). The INTRA-MODULAR LINKS are described by the sequence: (2-2,2-6,2-12,2-12,2-12,2-12,2-6,2-2), while the INTER-CONNECTING LINKS are expressed as: (2,2,2,2,2,2,2,2,2,2,2,2) or as (2x11). The INTER-CONNECTING LINK MODE is loosely spiral over the surface of the stent column. The STENT LENGTH is 20-25 mm. The END PIECES comprise two solo rings (28) on each end of the stent of FIG. 19.

FIG. 20 shows a further variation from the stent 11 of FIG. 19. In FIG. 20, it is seen that the double solo end pieces on either end of the stent 11 are reduced to single solo ring units 28. Other parameters are exactly same as Figure 19. The MODULAR

PATTERN is thus expressed as: (1,2,2,2,2,2,2,2,2,1). The INTER-CONNECTING LINKS are: (2,2,2,2,2,2,2,2,2) or (2x9). The END PIECES are (1xsolo:solox1) or single solo ring unit 28 on each end of the stent.

FIG. 21 illustrates yet another variation of stent programming. The stent 11 shown in FIG. 21 is distinguished form the stent of FIG. 20 in that the single solo ring units 28 on either end of the stent 11 have been removed. Thus, the end pieces of the stent of FIG. 21 are the 2-ring modules (70) of low density, with no changes of the center module (70) components. The RIGIDITY of the stent of FIG. 21 is symmetrically tapered from the center. FLEXIBILITY is progressively increased toward the periphery. Both ends of the stent 11 of FIG. 21 are slightly less flexible, because of the elimination of the end solo pieces. However, the flexibility of the remaining components of the stent 11 of FIG. 21 is no different from the central component of FIG. 19 or FIG. 20. The FRAME DENSITY of the stent of FIG. 21 is same as FIG. 19 or 20. The STENT RING PATTERN is unchanged from FIGS. 19 or 20. The MODULAR PATTERN is expressed as (2,2,2,2,2,2,2,2). The INTRA-MODULAR LINKS are characterized as: (2-2,2-6,2-12,2-12,2-12,2-12,2-6,2-2). The INTER-CONNECTING LINKS are as follows: (2,2,2,2,2,2,2) or (2x7). The INTER-CONNECTING LINK MODE is loosely spiral. This STENT LENGTH is about 20-22 mm. The END PIECES are (2-2 module : module 2-2), or each end has one unitized two (n=2) link 2-ring module.

FIG. 22 shows still a further variation of the stent of FIG. 21. In FIG. 22, a stent is illustrated that has been shortened from the stent of FIG. 21. That is, the 2-ring module 70 at either end of the stent 11 of FIG. 21 is broken up and removed, leaving one single or solo free ring unit 28 at each end of the stent of FIG. 22. The RIGIDITY, FLEXIBILITY, and FRAME DENSITY of the remaining components of the stent of FIG. 22 remain unchanged from FIG. 21. The STENT RING PATTERN remains as alternating trapezoidal cycles. The MODULAR PATTERN of the stent of FIG. 22 is now: (1,2,2,2,2,2,2,1), while the INTRA-MODULAR links are: (2-6,2-12, 2-12,2-12,2-12,2-6). All the remaining 2-ring (28) modules have high and medium density settings. The INTER-CONNECTING LINKS are expressed as: (2,2,2,2,2,2,2) or (2x7), and the INTER-CONNECTING LINK MODE remains as loosely spiral. The STENT LENGTH is further shortened to about 15-18mm. The END PIECE(S) are now made of (1 x single : single x 1), or a single solo ring unit 28 is located at each end.

FIG. 23 is another example how stent programming is used to create a variation from the stent matrix of FIG. 19. In FIG. 23, the two low density 2-ring (28) modules on the left end of the stent matrix of Figure 19 have been removed and have been replaced with a single solo ring 28 as an end piece. Therefor, the center of gravity of the stent 11

of FIG. 23 has been slightly shifted to the left. The total number of the 2-ring unitized modules 70 in the stent is now seven (n=7), and the total number of the basics ring units 28 used in this stent is seventeen (n=17). The parameters of the stent are detailed in the parameter box 84 of FIG. 23.

With respect to the stent 11 of FIG. 23, the RIGIDITY is now asymmetrically tapered; with the rigidity tapering more extended to the rightward direction and higher rigidity and scaffolding strength moved to left side of the stent. The FLEXIBILITY is also more progressive toward the right ward direction; with left end flexibility being slightly less than the right end due to the shifting of the center of gravity to the left side of the stent. The FRAME DENSITY of the stent of FIG. 23 is asymmetrically accelerated to the left. The MODULAR PATTERN for the stent of FIG. 23 may be expressed as follows: (1,2,2,2,2,2,2,2,1,1). The INTRA-MODULAR LINKS are expressed as follows: (2-6,2-12,2-12,2-12,2-12,2-6,2-2) The INTER-CONNECTING LINKS are as follows: (2,2,2,2,2,2,2,2,2) or (2x9). The STENT LENGTH is about 20-25 mm. The end pieces are: (1 x single : single x 2).

FIG. 24 shows a further variation of the stent of FIG. 23. The stent 11 of FIG. 24 is further shortened by removing the solo 28 end piece 28 from the left end of the stent; thus shifting the center of gravity even further to the left side from that of the stent in FIG. 23. As a result, most of the 2-ring modules 70 of the stent of FIG. 24 are located in the left half of the stent 11.

The RIGIDITY of the stent of FIG. 23 is asymmetrically tapered; with a very flexible right end and a moderately flexible left end. The FLEXIBILITY is more progressively extended to the right; by shifting the rigidity center to the left. The FRAME DENSITY is asymmetrically accelerated to the left; with the high density center moved to the left of the center. The STENT RING PATTERN is not changed. The MODULAR PATTERN is: (2,2,2,2,2,2,2,1,1). The programmed INTRA-MODULAR LINKS are: (2-6,2-12,2-12,2-12,2-12,2-6,2-2). The INTER-CONNECTING LINKS are: (2,2,2,2,2,2,2,2) or (2x8). The INTER-CONNECTING LINK MODE is loosely spiral. The STENT LENGTH is about 18-20mm. The END PIECES are: (2-6 module : single x 2) or one 2-ring module (unitized by 6 links) is on the left end and two single (solo) basic ring units 28 are on the right end.

Referring next to FIG. 25, a further shortening of the stent 11 of FIG. 24 is shown by removing another 2-ring module 70 from the left end of the stent. Now, as seen in FIG. 24, the high density rigidity center is located in the middle of left half of the stent. In the stent of FIG. 24, there are now six 2-ring modules 70 and two single (solo) basic ring units 28. The RIGIDITY of the stent of FIG. 25 is still tapered in the rightward

direction asymmetrically. The FLEXIBILITY is progressively extended to the right; with the flexibility center being shifted to the right half of the stent 11 (FIG. 25). FRAME DENSITY is also accelerated to the right with the density center in the left half of the stents. The MODULAR PATTERN is now as: (2,2,2,2,2,2,1,1). The INTRA-MODULAR LINKS are: (2-12,2-12,2-12,2-12,2-6,2-2). The INTER-CONNECTING LINKS are: (2,2,2,2,2,2,2) or (2 x 7). The STENT LENGTH is about 15-18mm. The INTER-CONNECTING MODE is still loosely spiral. The END PIECES are: (2-12 module : single x 2) or one 2-ring module 70 unitized by 6 bridging links on the left end and two solo basic ring units 28 on the right end.

Turning now to FIG. 26, another stent 11 made in accordance with the invention is illustrated. The stent illustrated in FIG. 26 has a relatively high density format. Although the length of the stent 11 shown in FIG. 26 is relatively short (e.g.- about 12-15 mm), the modular features shown in connection with the stent of FIG. 26 may, of course, be programmed into a stent of any desired length. Furthermore, it is noted that a stent made pursuant to the teachings of the present invention does not need to have only one center. Rather, any number of density or rigidity centers can be programmed into one stent; thereby providing multiple repeating density or rigidity centers within the stent. The versatile programming capability provided by the present invention allows one to program an enormous variety of length, rigidity, flexibility and density choices into a stent, using a simple pattern as has been shown in the figures discussed above, or in complex patterns in which a simple pattern effectively repeats in one stent.

The parameters associated with the stent of FIG. 26 are as follows: The RIGIDITY is asymmetrically tapered. The FLEXIBILITY is progressively extended toward the right. The FRAME DENSITY is slightly more accelerated to the left. The MODULAR PATTERN is: (2,2,2,2,2,2,2). The INTRA-MODULAR LINKS are: (2-6, 2-12,2-12,2-12,2-12,2-6,2-2). The INTER-CONNECTING LINKS are: (2,2,2,2,2,2,2) or (2 x 7). The INTER-CONNECTING LINK MODE is loosely spiral. The STENT LENGTH is about 12-15 mm. The END PIECES are: (2-6 module : 2-2 module) or a 2-ring module (70) unitized with 6 links on the left end and a 2-ring module (70) unitized with 2 links at the right end of the stent.

While the invention herein disclosed has been described by means of specific embodiments and applications thereof, numerous modifications and variations could be made thereto by those skilled in the art without departing from the scope of the invention set forth in the claims.

CLAIMS

What is claimed is:

1. A programmable, variably flexible modular stent comprising:

a plurality of basic ring units made from a thin-walled malleable material, each basic ring unit having a recurring sequence of circumferential segments and circumferential/longitudinal segments; and

at least one bridging link that longitudinally connects a circumferential segment of each basic ring unit to a corresponding circumferential segment of an adjacent basic ring unit;

the basic ring units connected to each other with said at least one bridging link thereby forming a tubular-shaped stent frame, which tubular-shaped stent frame assumes a pre-expanded size having a first diameter when the circumferential/longitudinal segments of the basic ring units are oriented to lie predominantly in a longitudinal direction, and which tubular-shaped frame assumes an expanded size having a second diameter when the circumferential/longitudinal segments of the basic ring units are bent to lie predominantly in a circumferential direction, wherein the second diameter of the tubular-shaped frame is greater than the first diameter;

whereby the stent frame, when in its pre-expanded size, may be inserted into the lumen of a vessel having a diameter greater than the first diameter, and the stent frame, once inserted into a desired location of the lumen, may then be expanded to assume its expanded size, thereby providing an expanded stent frame which thereafter serves as a supporting structure to hold the lumen open with an open diameter of approximately said second diameter.

2. The stent of Claim 1 wherein the basic ring unit comprises a symmetrical alternating trapezoidal cycle ring having four recurring segments, two of which follow circumferential paths which are substantially parallel to each other, and two of which follow circumferential/longitudinal paths which are not parallel to each other.

3. The stent of Claims 1 or 2 wherein the second diameter is at least twice the first diameter.

4. The stent of Claims 1 or 2 wherein at least a portion of the basic ring units within the stent are joined to form a plurality of modules, wherein each module comprises

a plurality of basic ring units joined together by a selected number of bridging links of a fixed length, the fixed length, number and circumferential location of the bridging links determining in large part the flexibility and density characteristics of the module.

5. The stent of Claim 4 wherein modules of differing flexibility and density are joined together to provide a stent exhibiting variable flexibility and density along its length.

6. The stent of Claim 4 wherein the circumferential location of the bridging links of each ring unit is confined to a sector that comprises less than 180 degrees of the ring unit, and wherein said circumferential location follows a rough spiral pattern along the longitudinal axis of the stent frame.

7. The stent of Claims 5 or 6 wherein the stent comprises flexibly coupled and less dense ring units joined by fewer and longer bridging links at each end of the stent, and less flexibly coupled and more dense ring units joined by more and shorter bridging links near the center of the stent.

8. The stent of Claims 5 or 6 wherein the stent comprises increasingly less flexibly coupled and more dense ring units, joined by increasingly more and shorter bridging links from one end of the stent towards the other end, whereby the stent exhibits flexibility and strength characteristics that taper from one end of the stent towards the other end.

9. An improved intravascular stent for implantation and deployment within the lumen of a vessel, the sent having a pre-enlarged diameter which facilitates its insertion into the lumen of the vessel, the stent having means for expanding its diameter to an enlarged diameter which supports and holds open the lumen, the stent being characterized by:

a multiplicity of basic circular ring units of alternating trapezoidal cycles arranged and connected to form a tubular frame; and

at least one bridging link that connects each of the basic circular ring units to an adjoining basic circular ring unit, wherein the number, length, and circumferential location of the bridging link(s) is programmed to set the flexibility/rigidity and density/strength of the stent.

10. A method of making an intravascular stent comprising:

cutting a prescribed stent pattern out of a small diameter and thin-walled metal tube, the prescribed stent pattern being characterized by

forming and arranging a multiplicity of basic circular ring units of alternating trapezoidal cycles to form a tubular frame;

connecting at least one bridging link between each of the basic circular ring units and an adjoining basic circular ring unit, and

programming the number, length, and circumferential location of the bridging link(s) to set the flexibility/rigidity and density/strength of the stent.

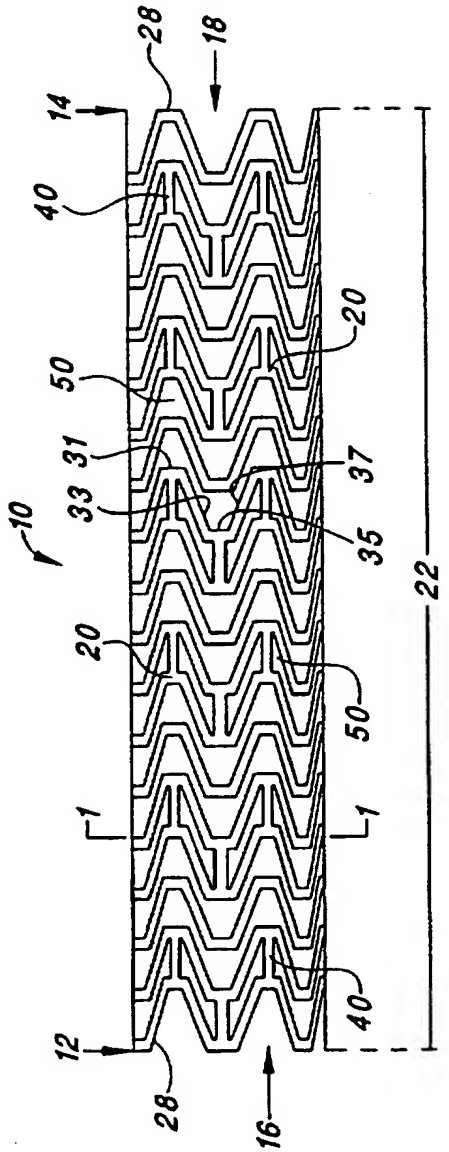

FIG. 1-A

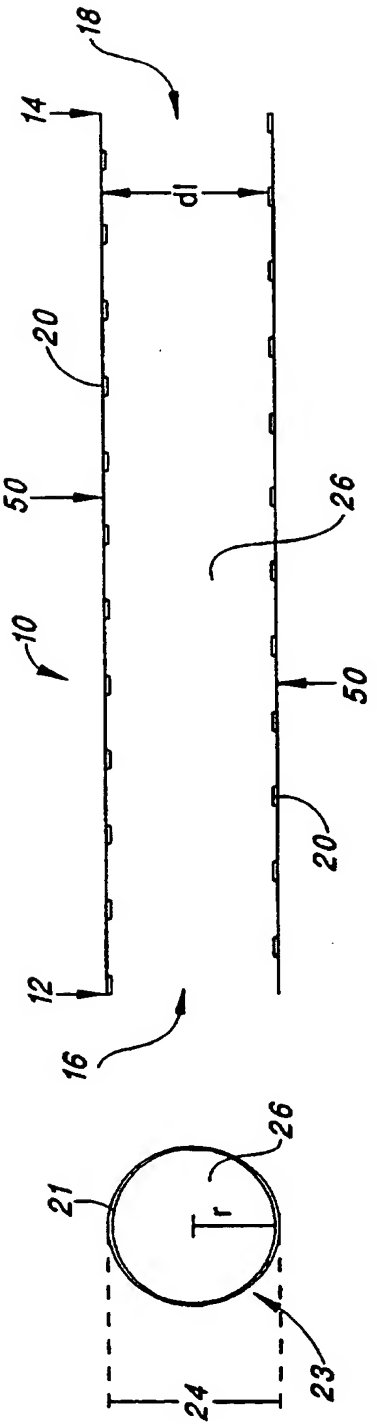

FIG. 1-B

FIG. 1-C

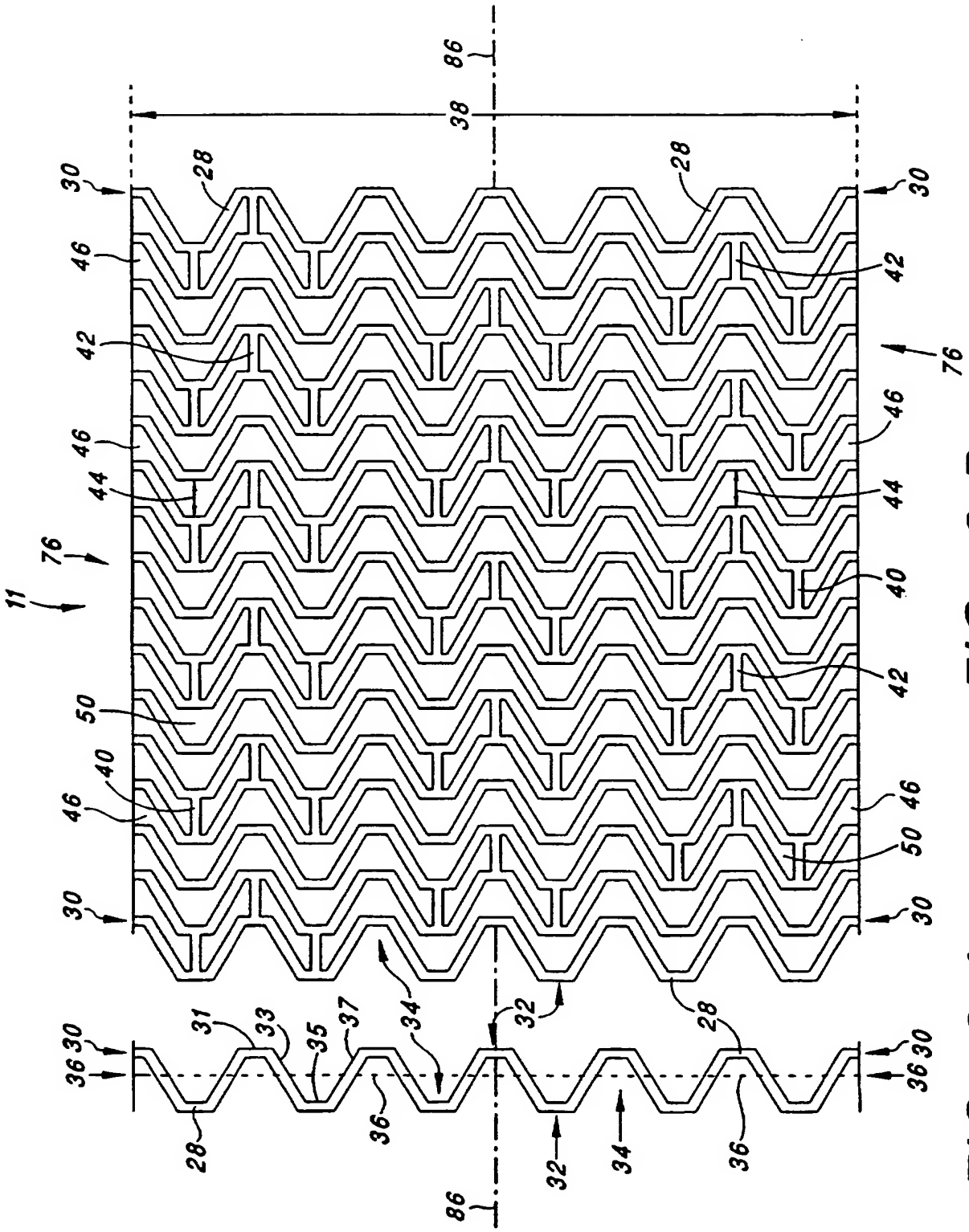

FIG. 2-A

FIG. 2-B

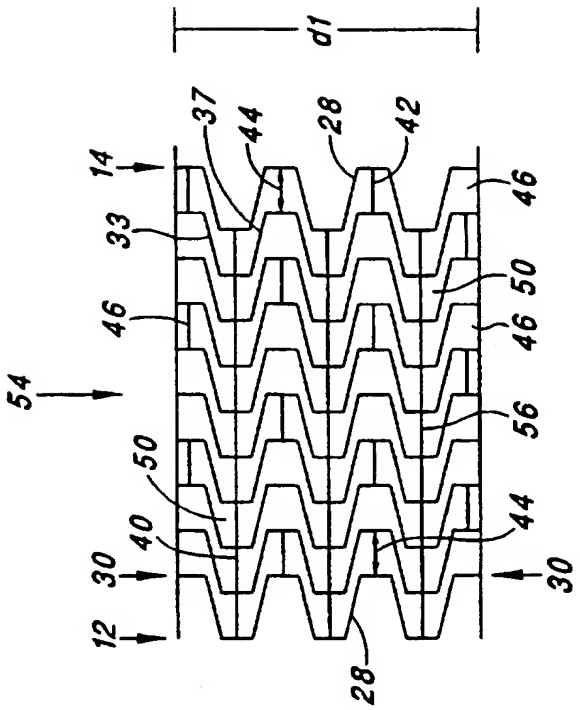

FIG. 3-B

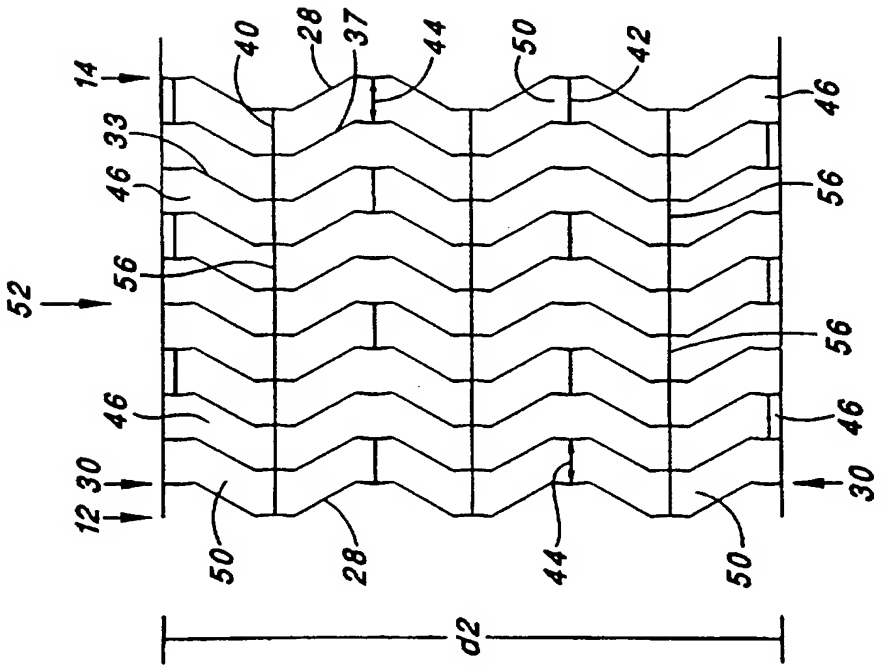

FIG. 3-A

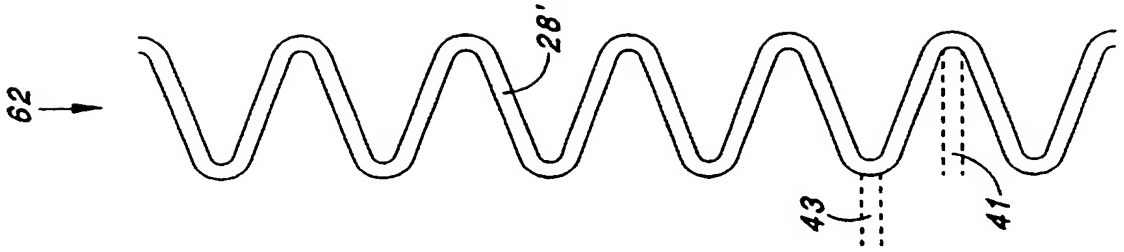

FIG. 4-D

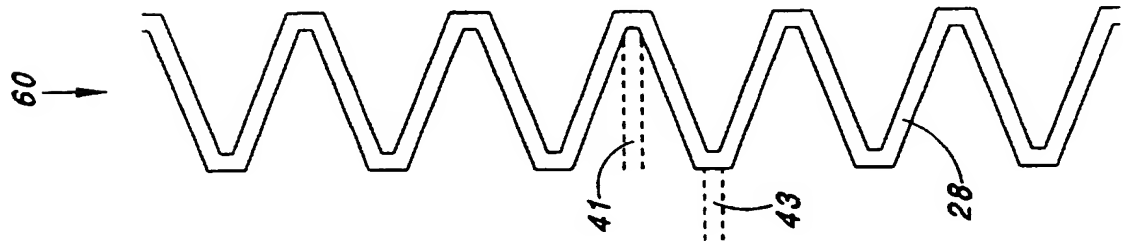

FIG. 4-C

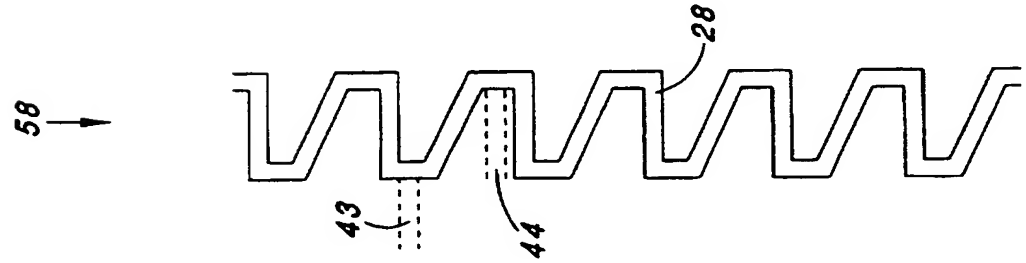

FIG. 4-B

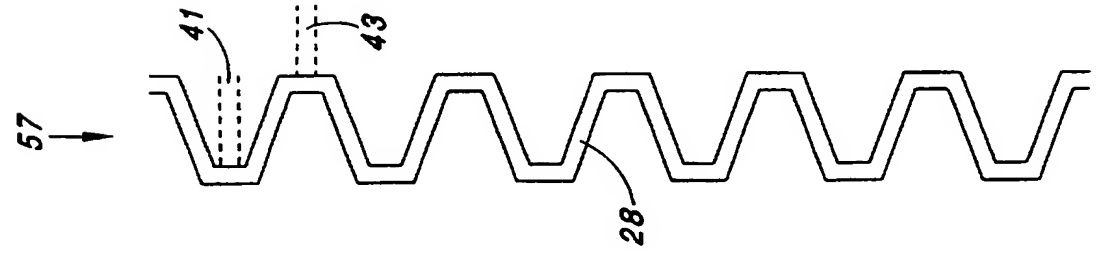

FIG. 4-A

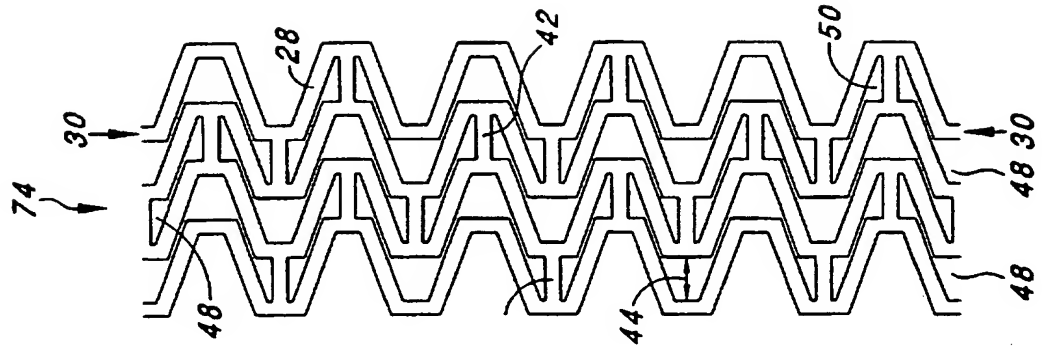

FIG. 9

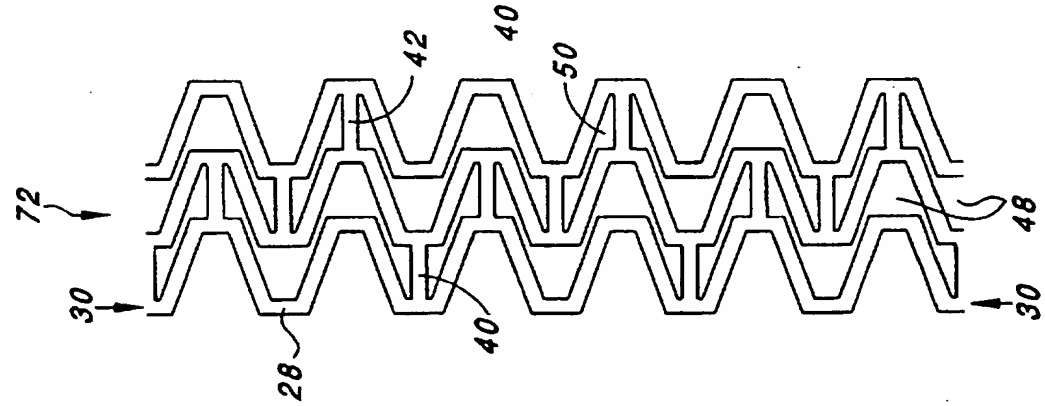

FIG. 8

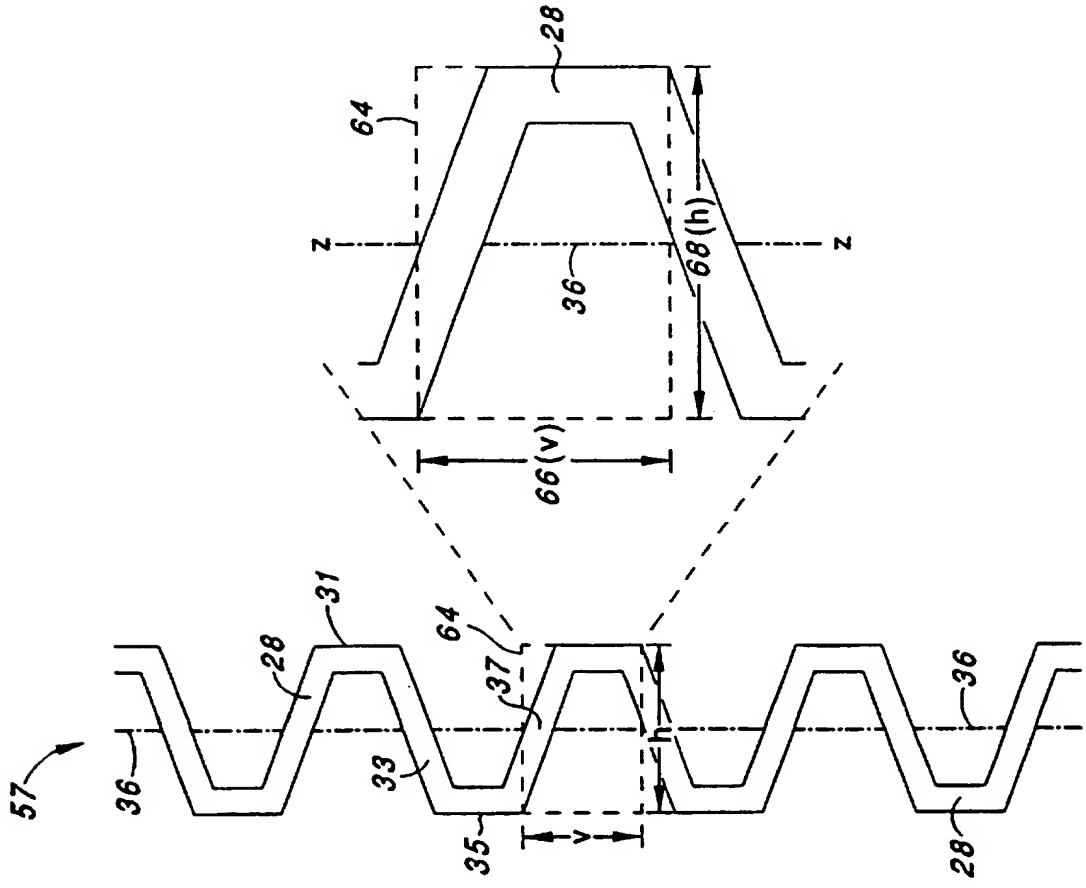

FIG. 5-B

FIG. 5-A

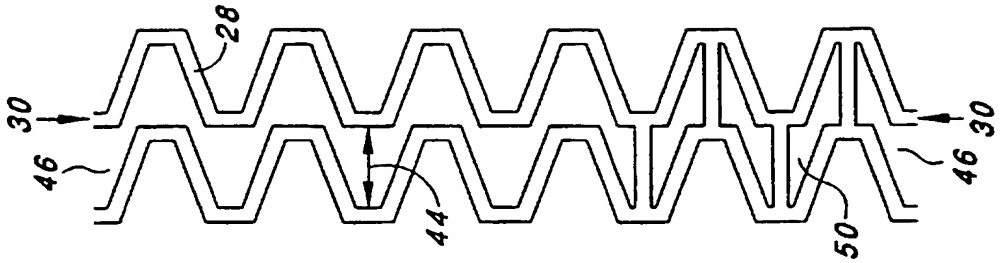

FIG. 6-E

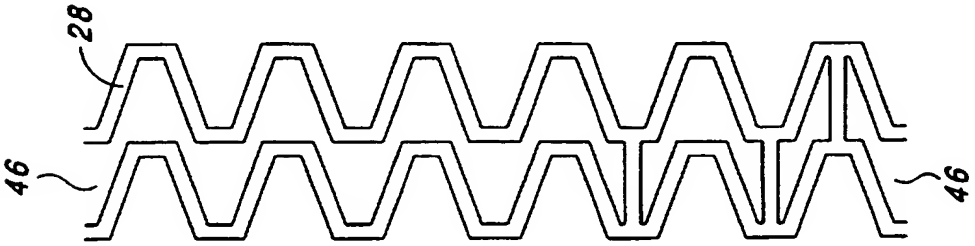

FIG. 6-D

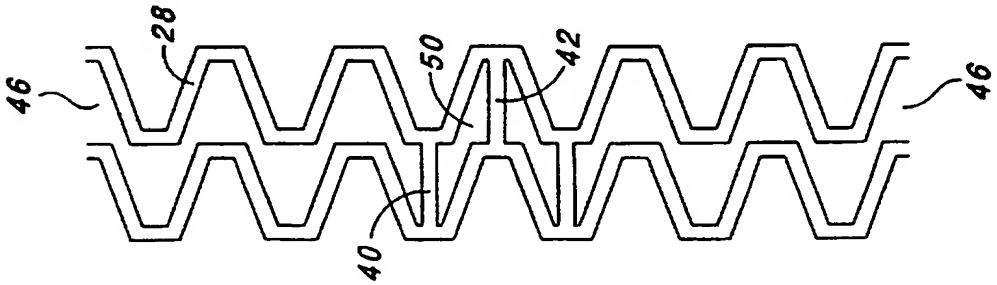

FIG. 6-C

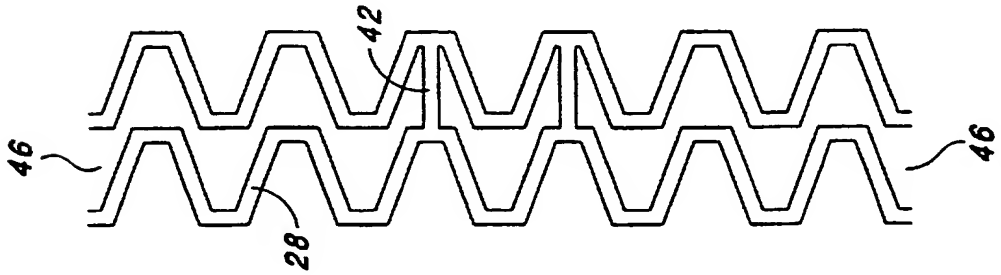

FIG. 6-B

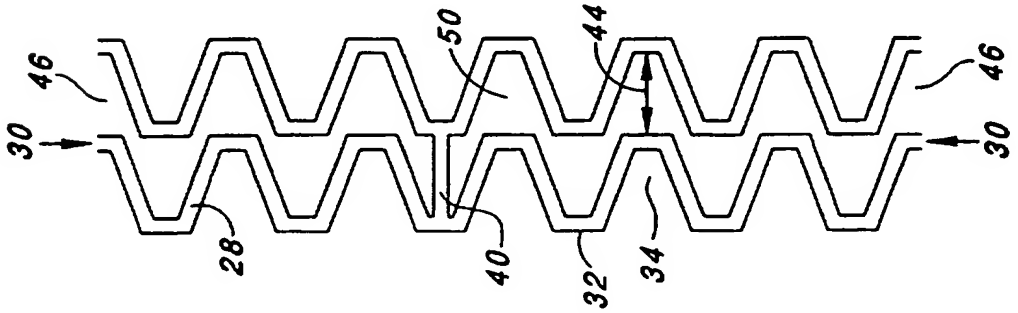

FIG. 6-A

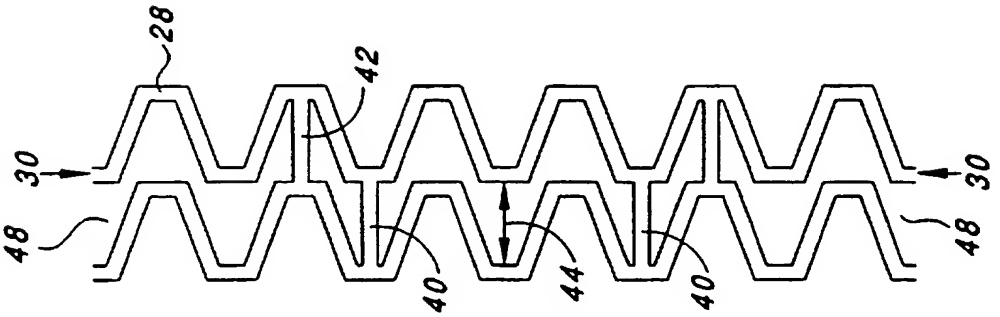

FIG. 6-J

FIG. 6-I

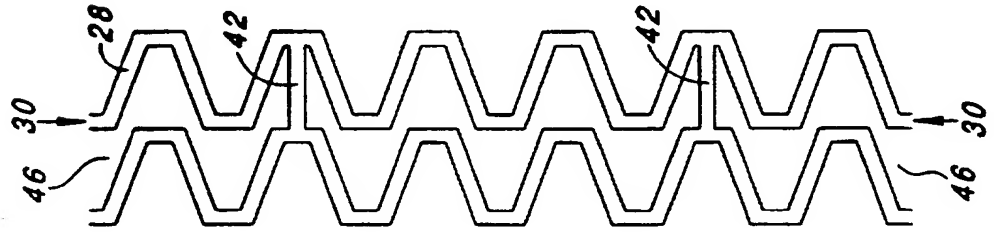

FIG. 6-H

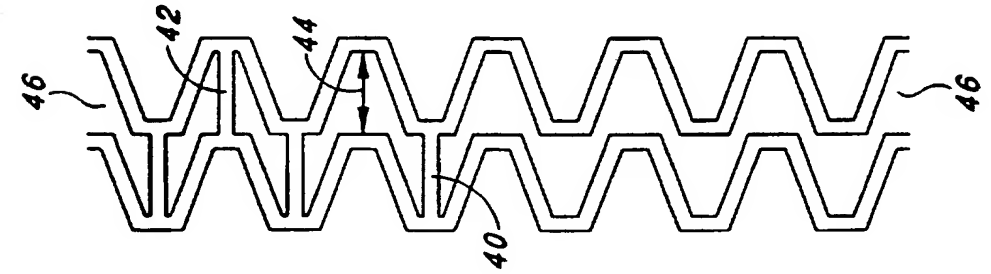

FIG. 6-G

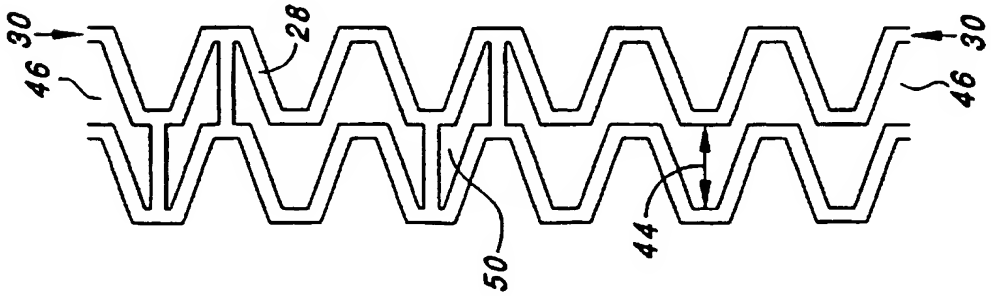

FIG. 6-F

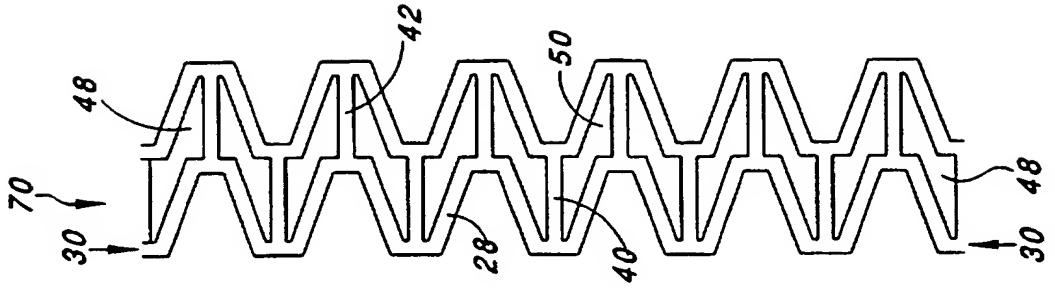

FIG. 7

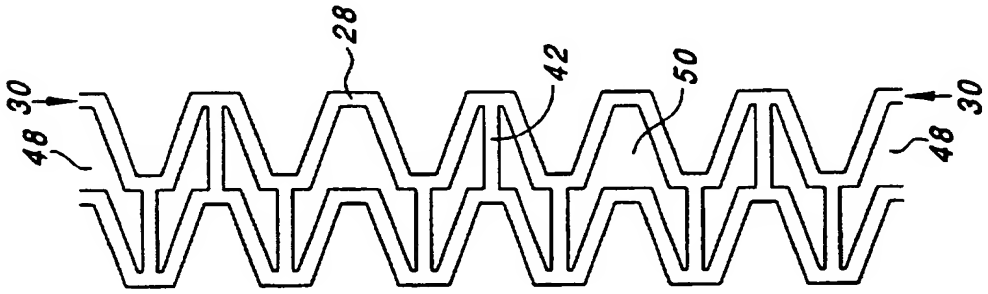

FIG. 6-M

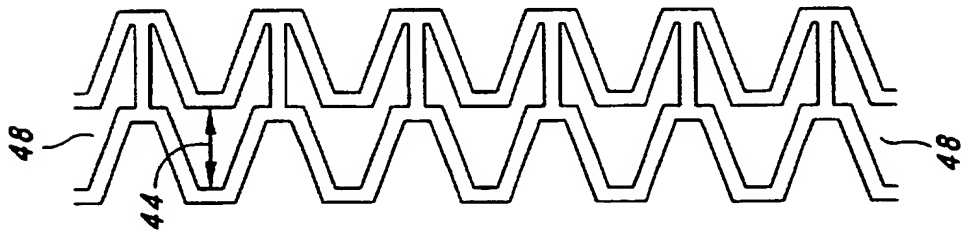

FIG. 6-L

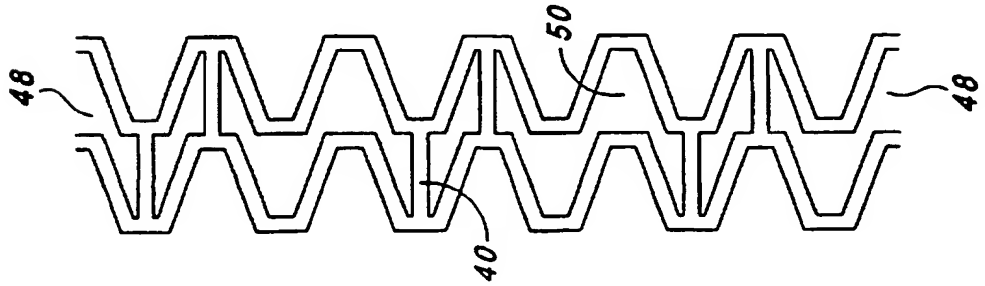

FIG. 6-K

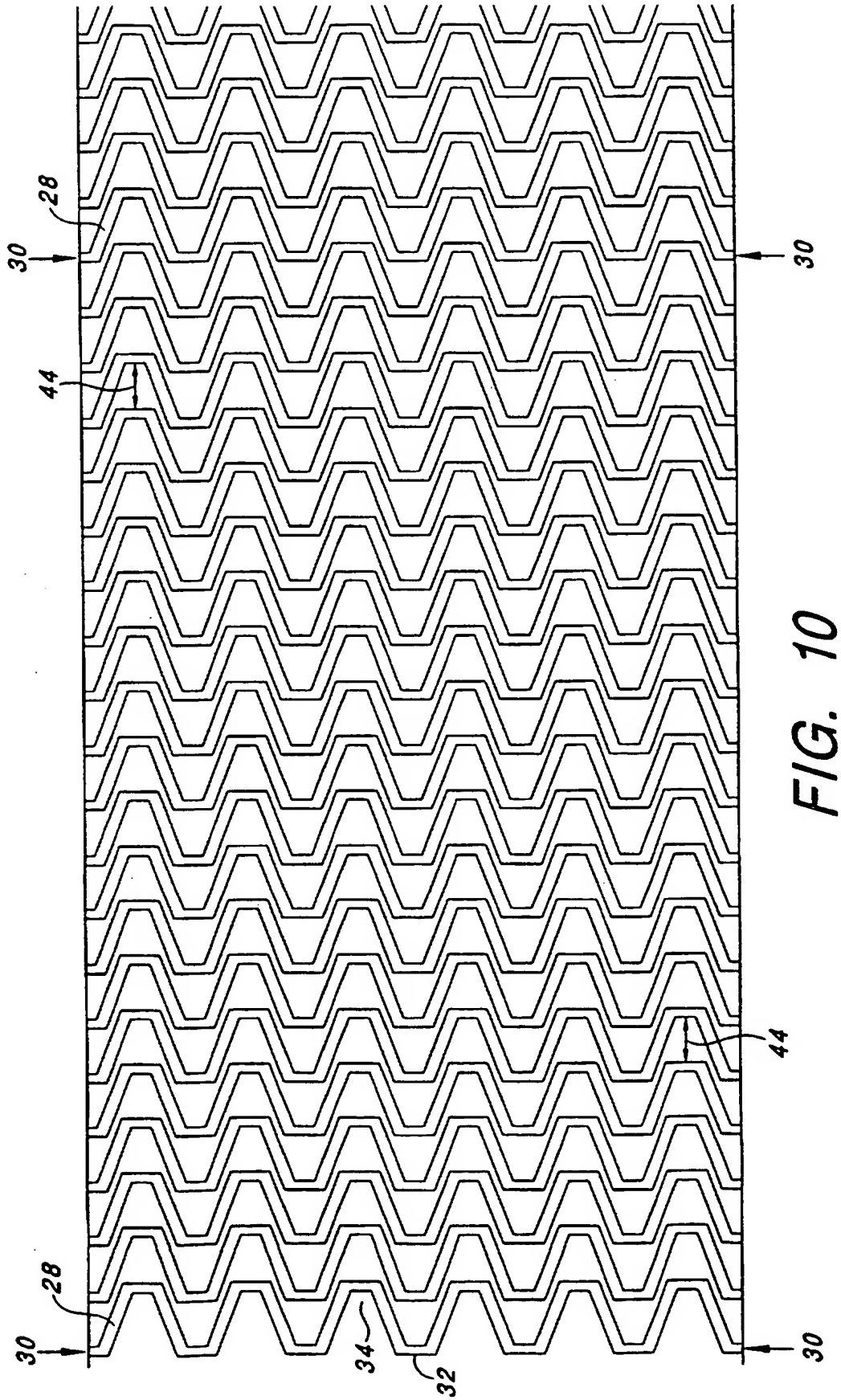

FIG. 10

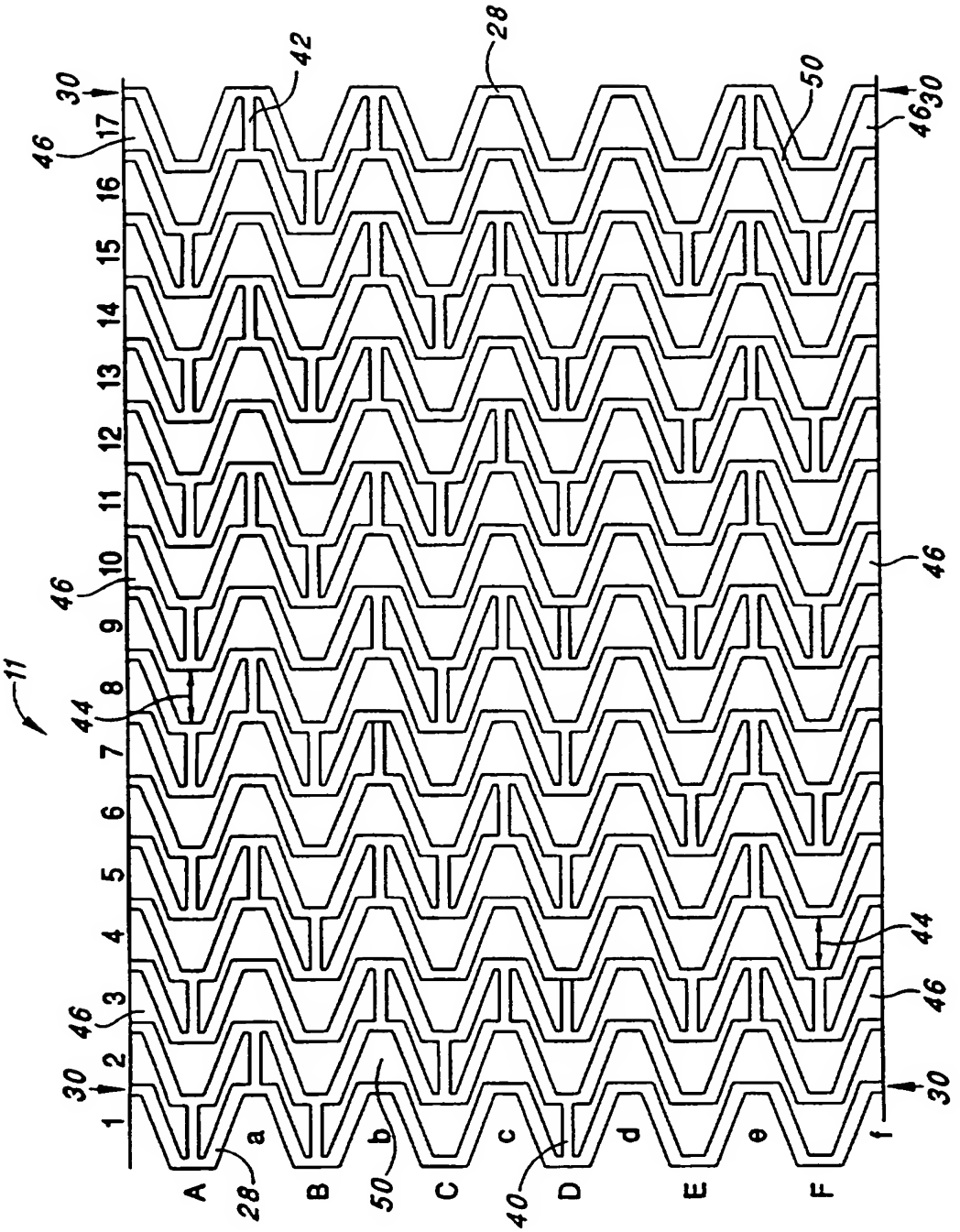

FIG. 11

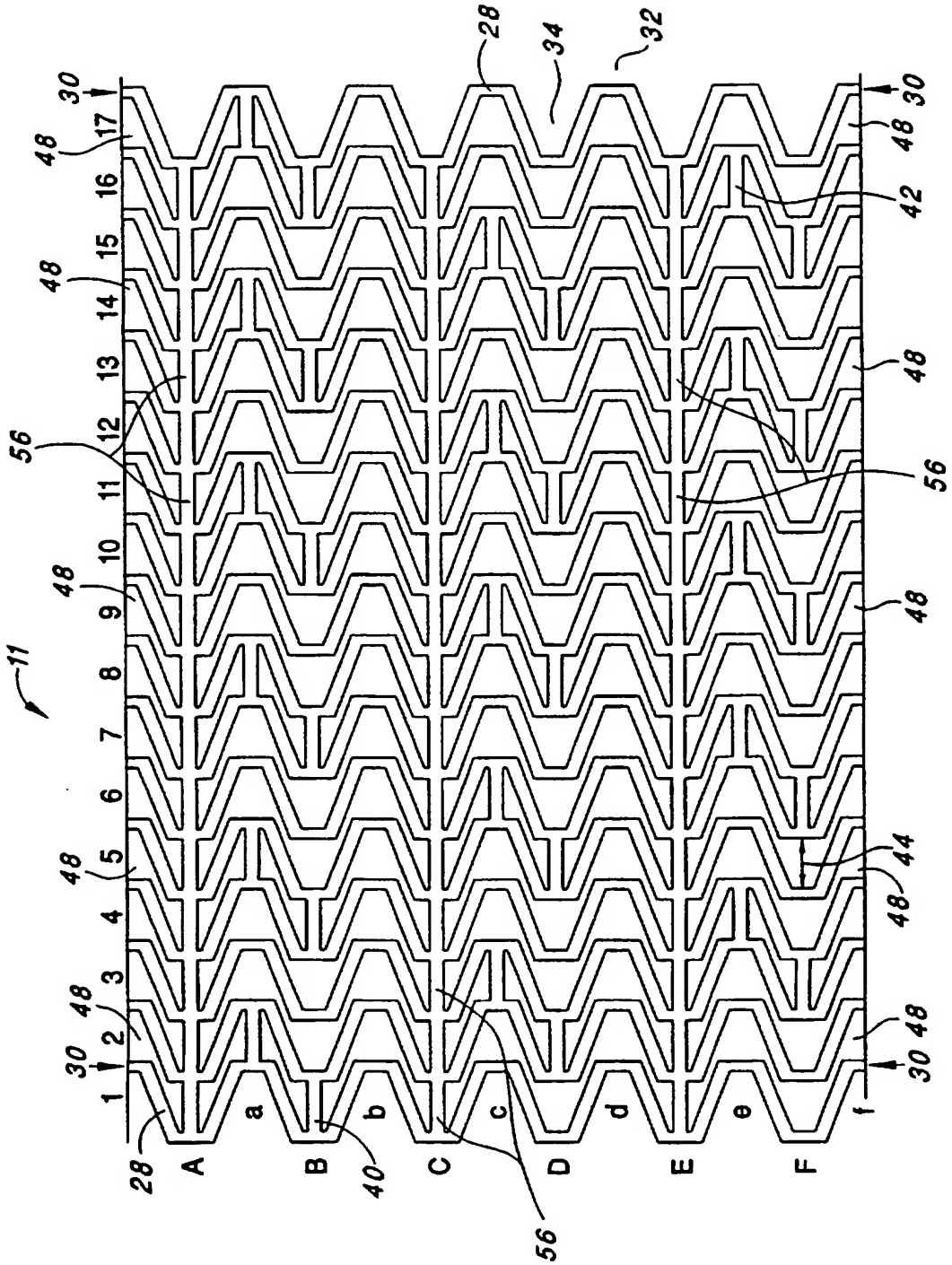

FIG. 12

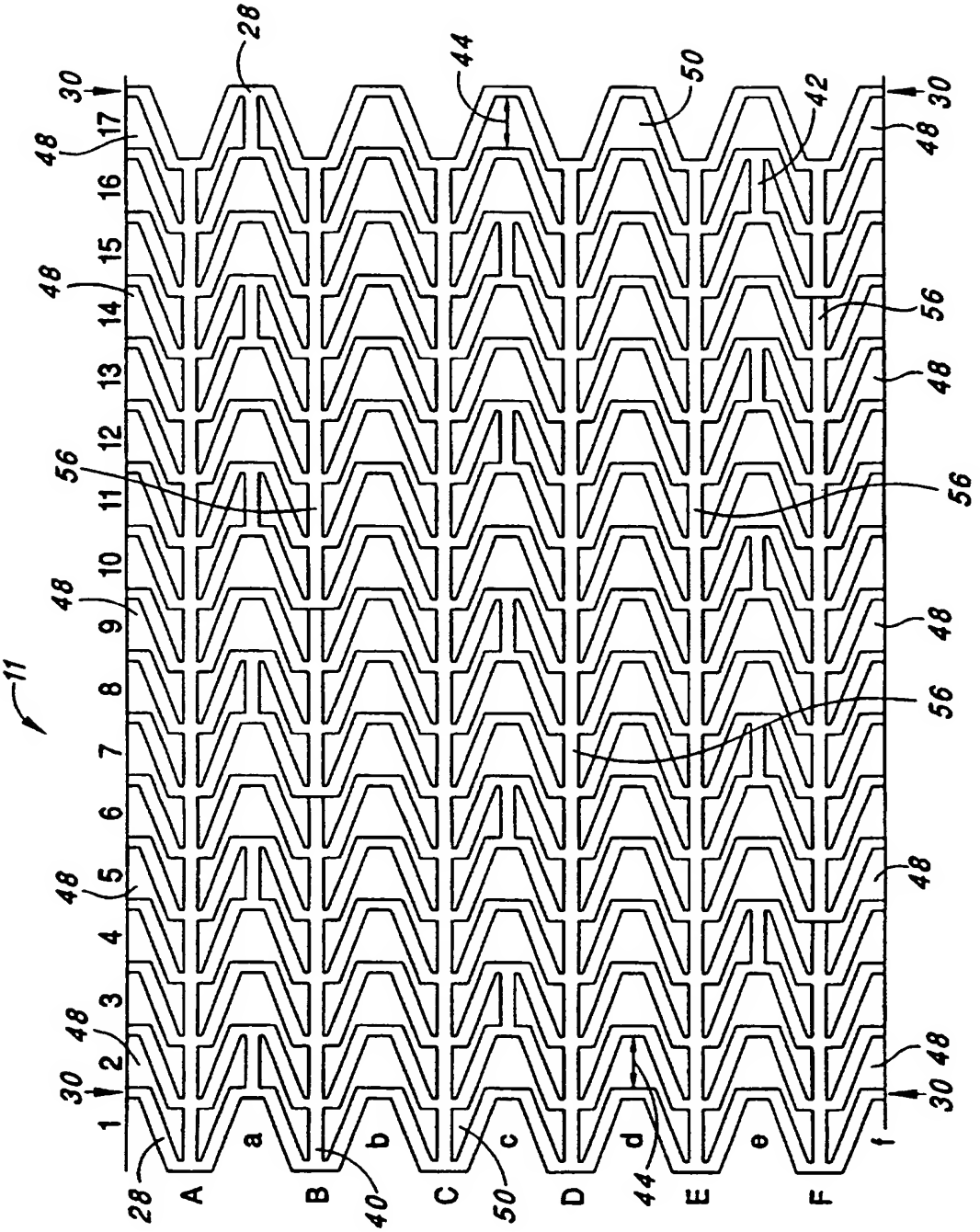

FIG. 13

RIGIDITY: • SYMMETRICALLY MODULAR ARRANGEMENT • MODERATE AT CENTER
FLEXIBILITY: • SYMMETRICALLY TAPERED • CENTER LESS FLEXIBLE
FRAME DENSITY: • UNIFORMLY SPACED
STENT RING PATTERN: • ALTERNATING TRAPEZOID CYCLES
MODULAR PATTERN: (1,1,2,3,1,3,1,3,2,1,1)
INTRA-MODULAR LINKS: (2-6,3-6,3-6,3-6,3-6,2-6)
INTRA-CONNECTING LINKS: (2,2,2,2,2,2,2,2,2,2,2) (2x10)
INTRA-CONNECTING LINK MODE: • LOOSELY SPIRAL
STENT LENGTH: • 15-20mm
END PIECE(S): • 2xSINGLES: SINGLESx2
INVENTION BY: • G. DAVID JANG, MD

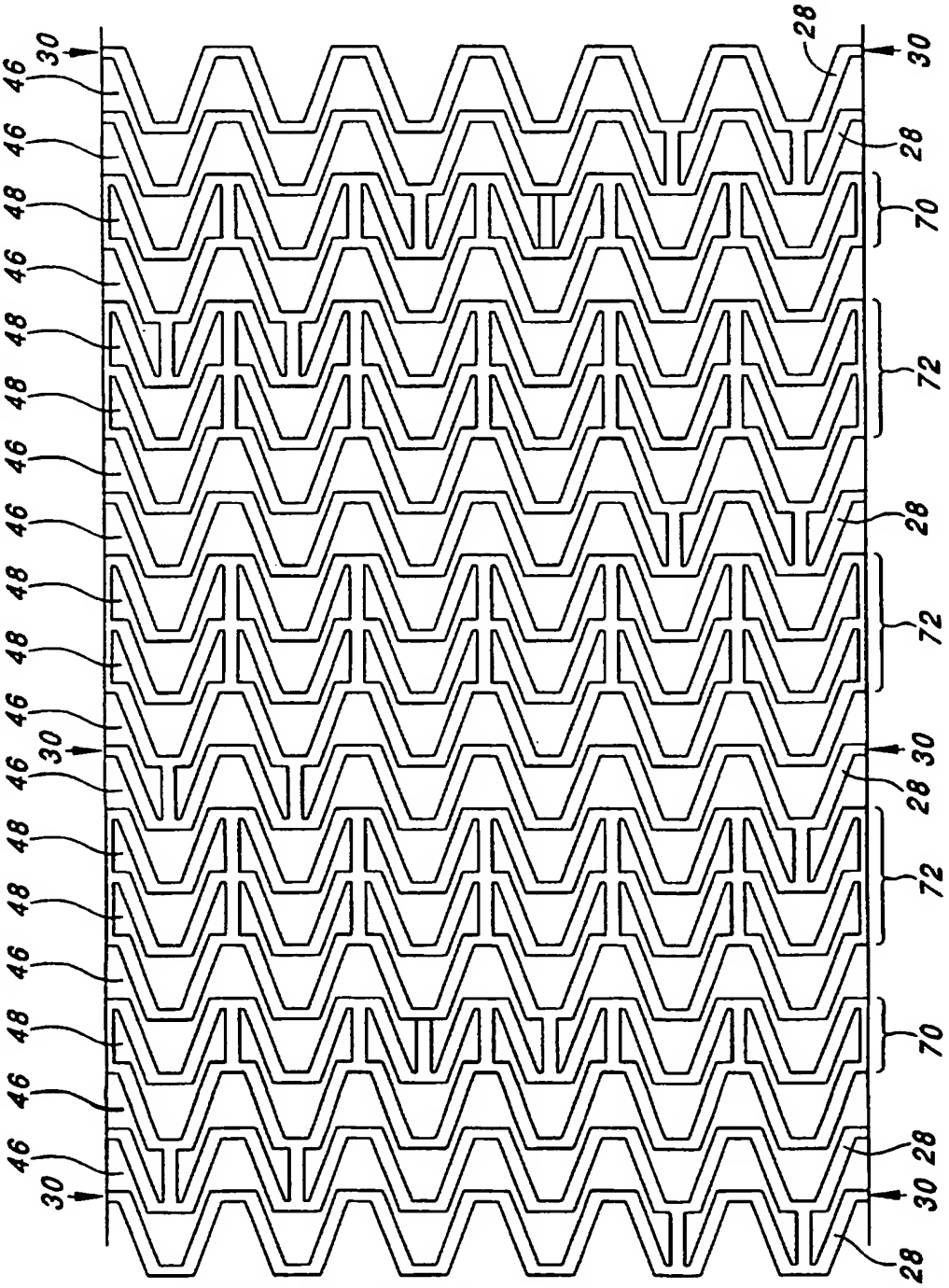

FIG. 14

84
RIGIDITY: • VARIABLE
FLEXIBILTY: • VARIABLE
FRAME DENSITY: • LOW-HIGH
STENT RING PATTERN: • ALTERNATING TRAPEZOID CYCLES
MODULAR PATTERN: • UN-CONNECTED
INTRA-MODULAR LINKS: • NONE
INTRA-CONNECTING LINKS: • NONE
INTRA-CONNECTING LINK MODE: • NONE
STENT LENGTH: • UN-CONSTRUCTED
END PIECE(S): • UNCONNECTED
INVENTION BY: • G. DAVID JANG, MD

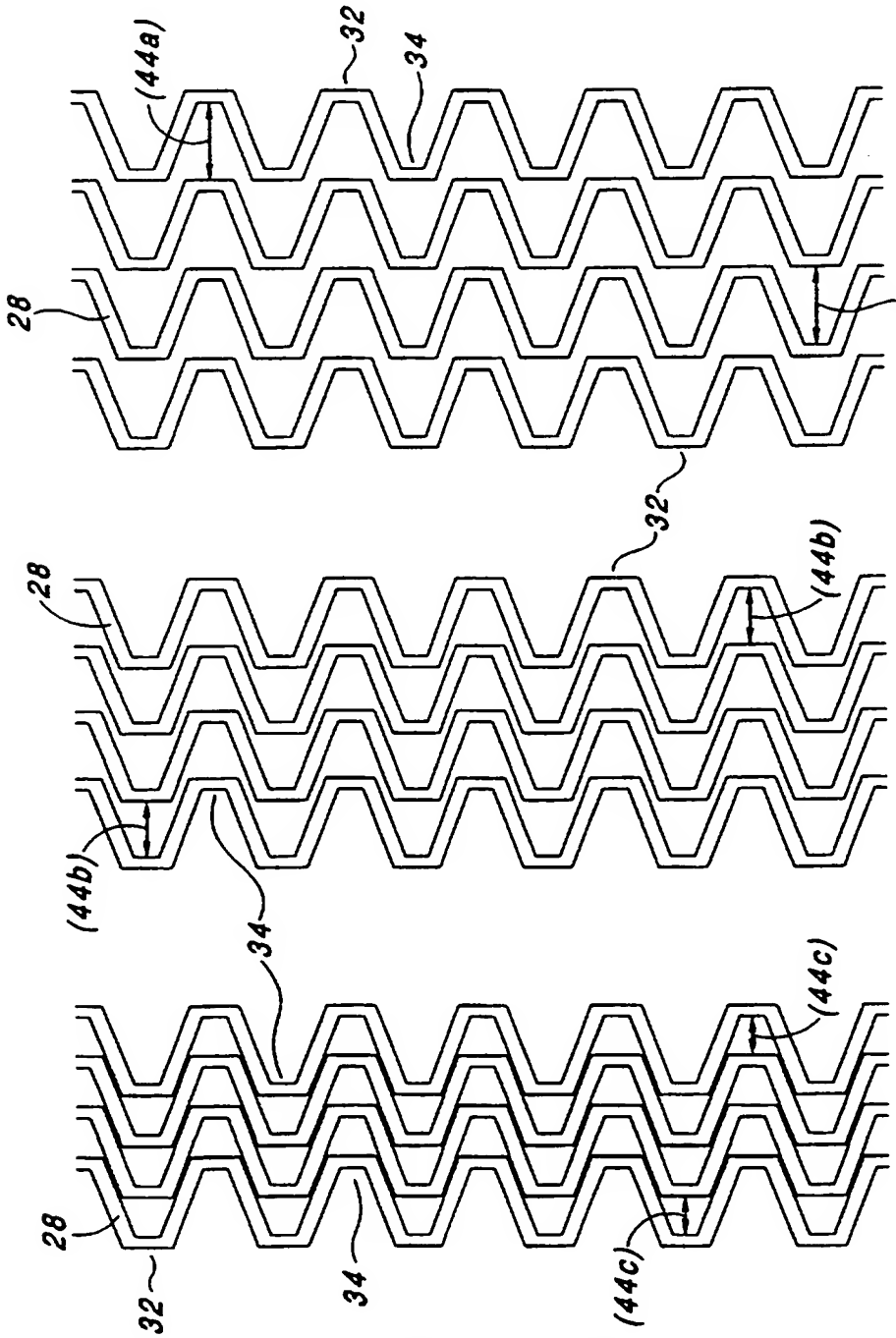

FIG. 15-A FIG. 15-B FIG. 15-C

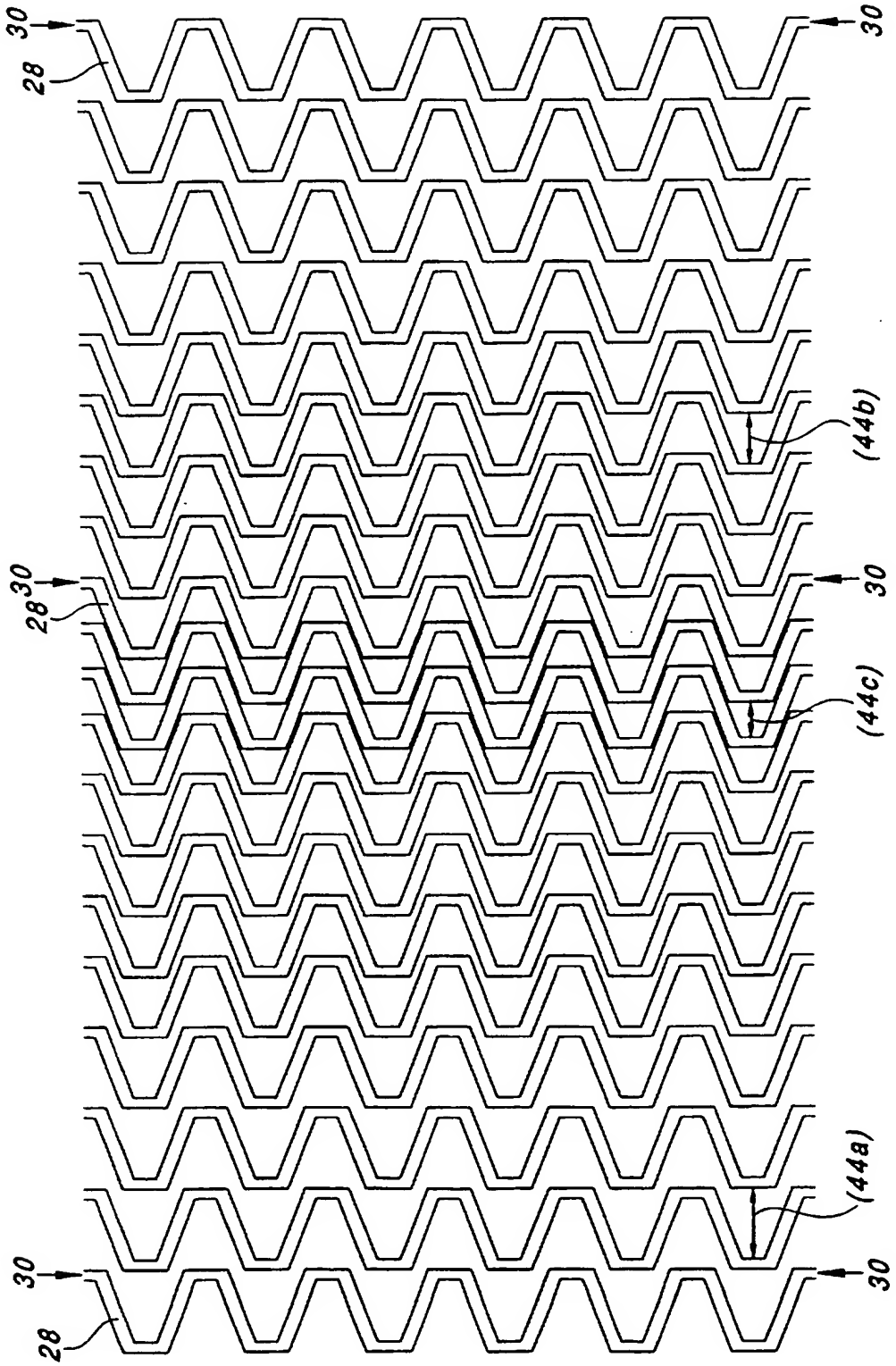

FIG. 16

RIGIDITY: • SYMMETRICALLY TAPERED FROM CENTER
FLEXIBILTY: • PROGRESIVE FROM CENTER
FRAME DENSITY: • ACCELERATED TO CENTER • CENTER-HIGH;MARGINS-LOW
STENT RING PATTERN: • ALTERNATING TRAPEZOID CYCLES
MODULAR PATTERN: (1,1,2,1,2,1,2,1,2,1,2,1,1)
INTRA-MODULAR LINKS: (2-4,2-12,2-12,2-12,2-12,2-12,2-4)
INTRA-CONNECTING LINKS: • UN-CONNECTED
INTRA-CONNECTING LINK MODE: • UN-CONNECTED
STENT LENGTH: • 25-30mm
END PIECE(S): • 2xSINGLES: SINGLESx2
INVENTION BY: • G. DAVID JANG, MD

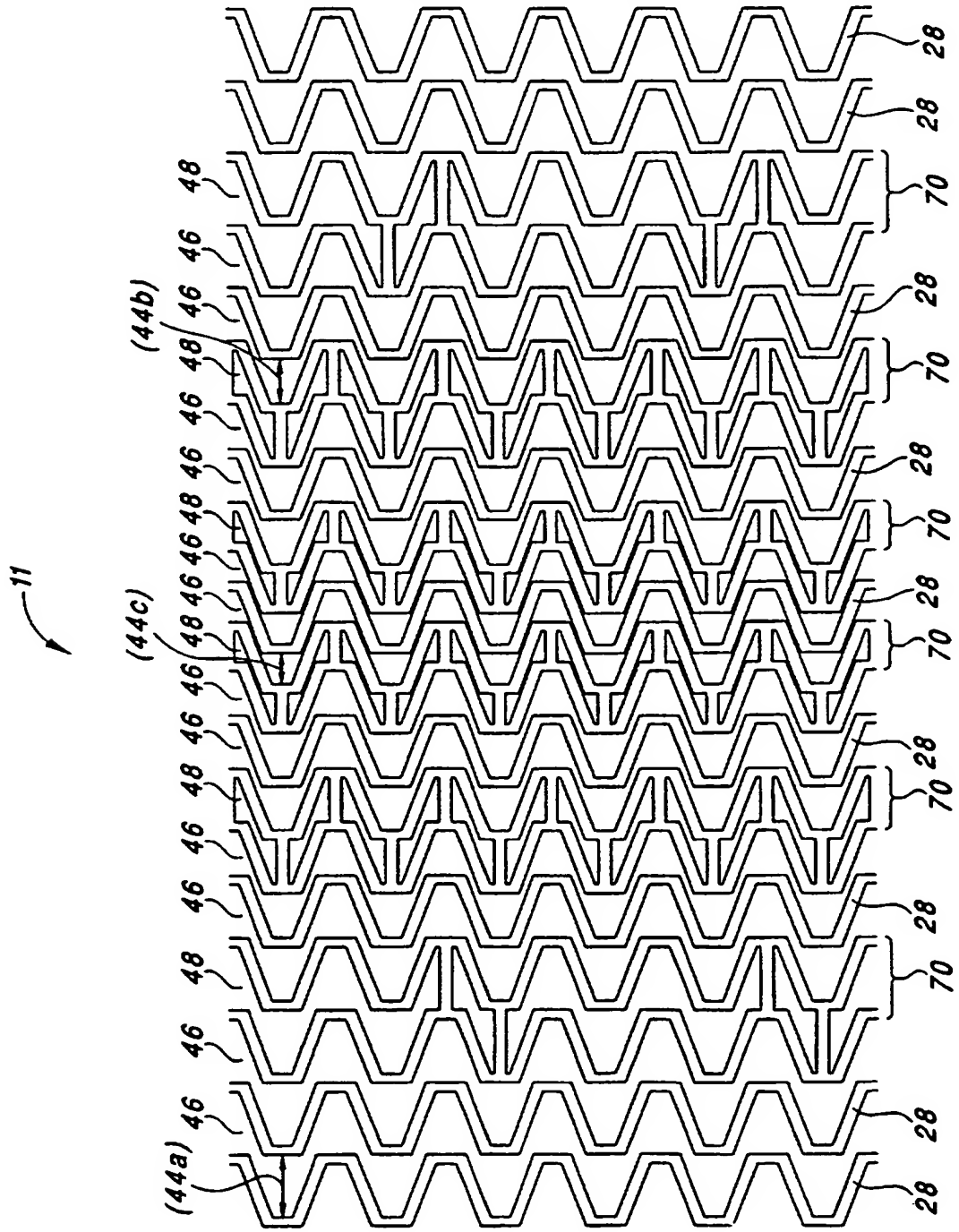

FIG. 17

RIGIDITY: • SYMMETRICALLY TAPERED FROM CENTER
FLEXIBILTY: • PROGRESIVE FROM CENTER
FRAME DENSITY: • ACCELERATED TO CENTER • CENTER-HIGH;MARGINS-LOW
STENT RING PATTERN: • ALTERNATING TRAPEZOID CYCLES
MODULAR PATTERN: (1,1,2,1,2,1,2,1,2,1,2,1,1)
INTRA-MODULAR LINKS: (2-4,2-12,2-12,2-12,2-12,2-4)
INTRA-CONNECTING LINKS: (2,2,2,2,2,2,2,2,2,2,2,2,2,2) (14x2)
INTRA-CONNECTING LINK MODE: • LOOSELY SPIRAL
STENT LENGTH: • 25-30mm
END PIECE(S): • 2xSINGLES: SINGLESx2
INVENTION BY: • G. DAVID JANG, MD

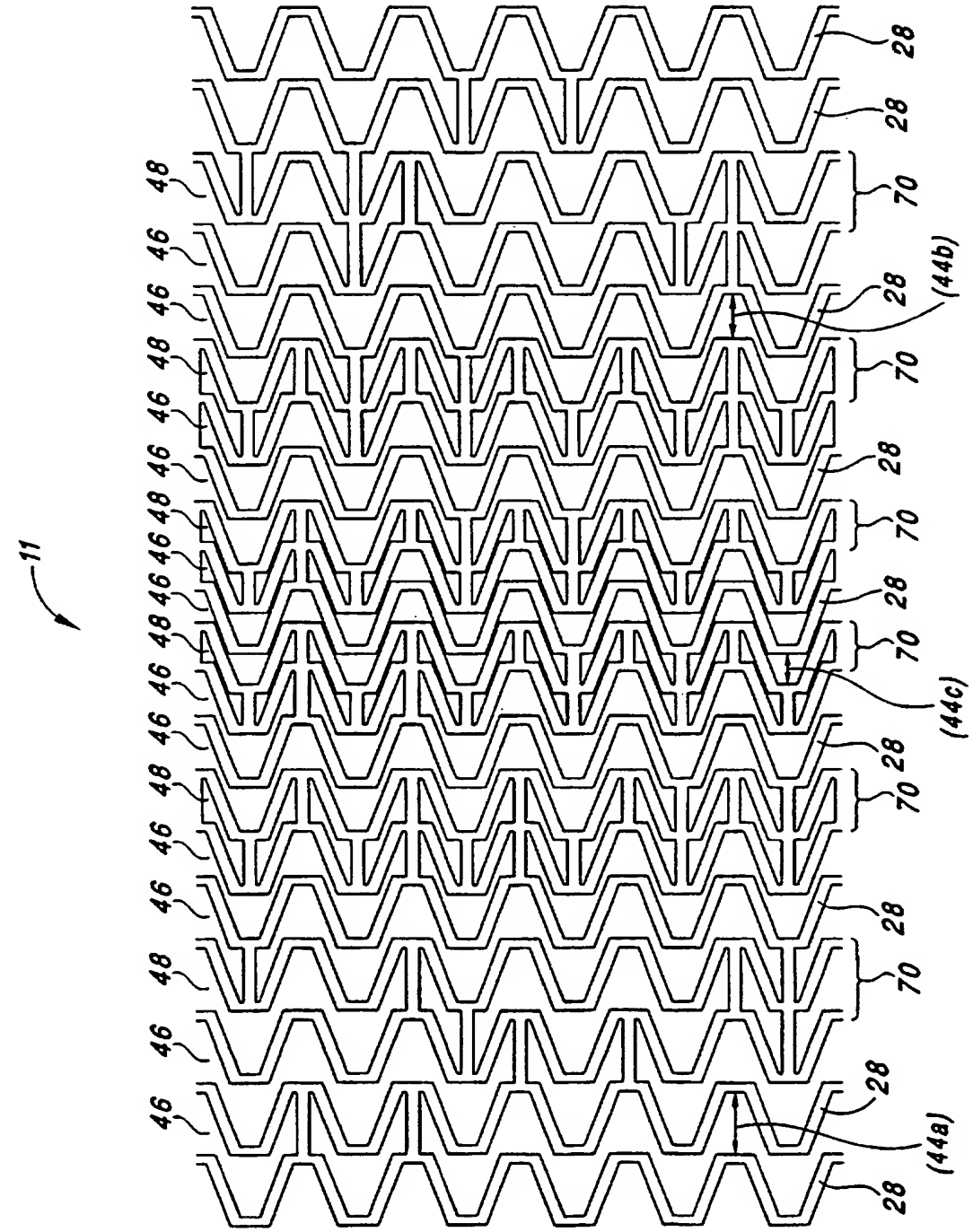

FIG. 18

RIGIDITY: • SYMMETRICALLY TAPERED FROM CENTER
FLEXIBILTY: • PROGRESIVE FROM CENTER
FRAME DENSITY: • ACCELERATED TO CENTER • CENTER-HIGH;MARGINS-LOW
STENT RING PATTERN: • ALTERNATING TRAPEZOID CYCLES
MODULAR PATTERN: (1,1,2,2,2,2,2,2,1,1)
INTRA-MODULAR LINKS: (2-2,2-6,2-12,2-12,2-12,2-12,2-6,2-2)
INTRA-CONNECTING LINKS: (2,2,2,2,2,2,2,2,2,2) (11x2)
INTRA-CONNECTING LINK MODE: • LOOSELY SPIRAL
STENT LENGTH: • 20-25mm
END PIECE(S): • 2xSINGLES: SINGLESx2
INVENTION BY: • G. DAVID JANG, MD

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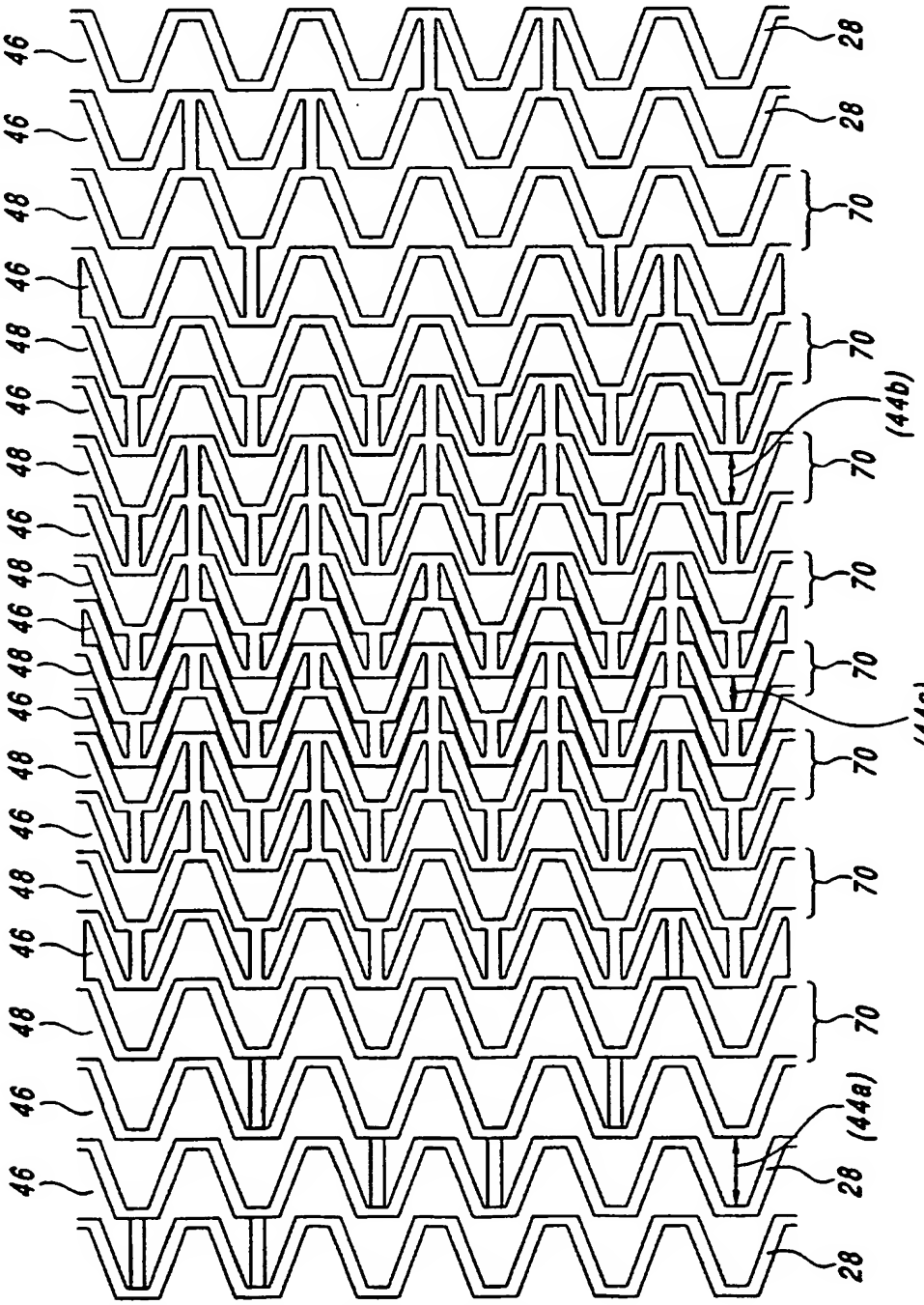

FIG. 19

RIGIDITY: • SYMMETRICALLY TAPERED FROM CENTER
FLEXIBILTY: • PROGRESIVE FROM CENTER
FRAME DENSITY: • ACCELERATED TO CENTER • CENTER-HIGH;MARGINS-LOW
STENT RING PATTERN: • ALTERNATING TRAPEZOID CYCLES
MODULAR PATTERN: (1,2,2,2,2,2,2,2,1)
INTRA-MODULAR LINKS: (2-2,2-6,2-12,2-12,2-12,2-12,2-6,2-2)
INTRA-CONNECTING LINKS: (2,2,2,2,2,2,2,2,2) (9x2)
INTRA-CONNECTING LINK MODE: • LOOSELY SPIRAL
STENT LENGTH: • 20-25mm
END PIECE(S): • 1xSINGLE: SINGLEx1
INVENTION BY: • G. DAVID JANG, MD

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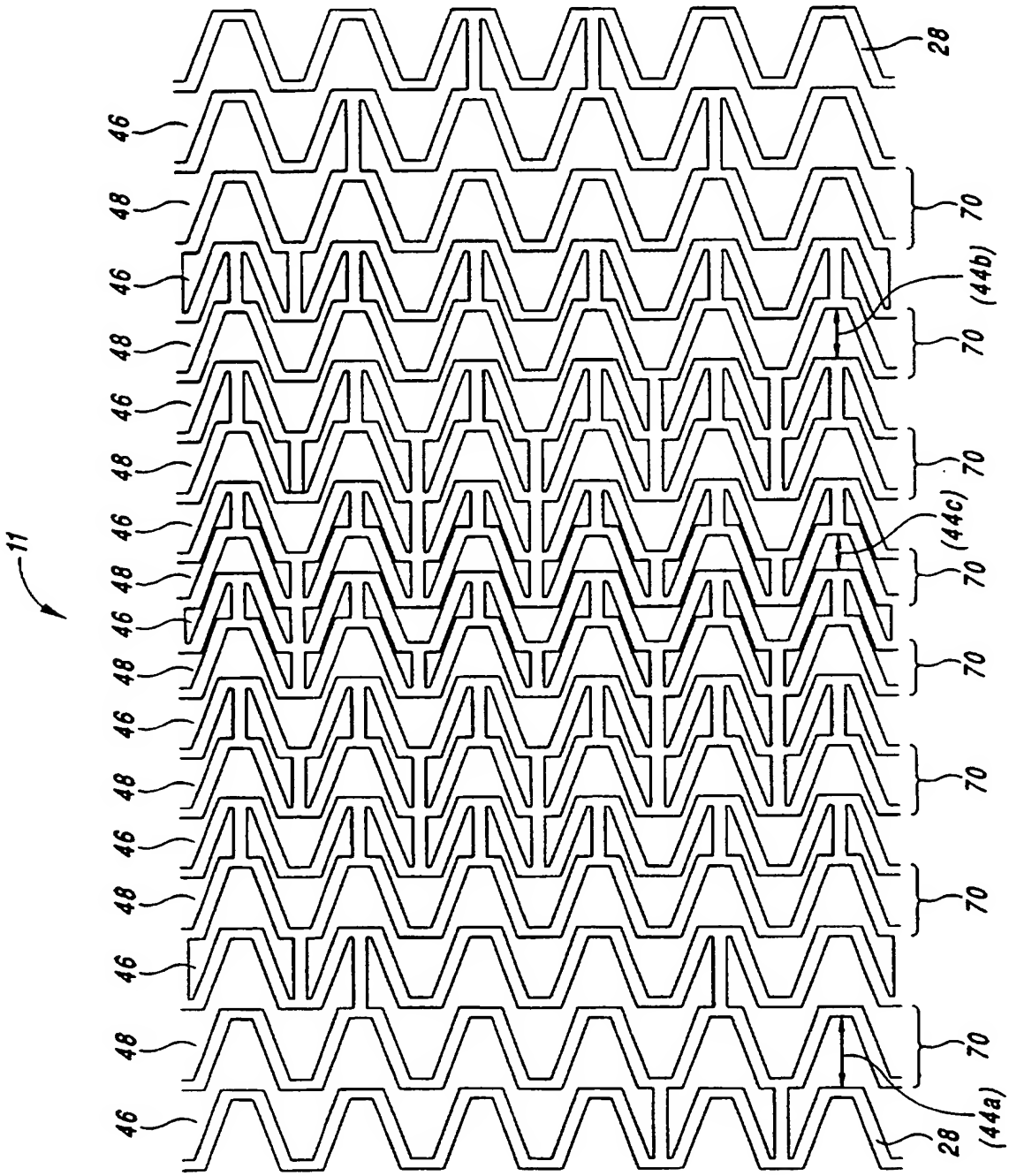

FIG. 20

RIGIDITY: • SYMMETRICALLY TAPERED FROM CENTER
FLEXIBILTY: • PROGRESIVE FROM CENTER
FRAME DENSITY: • ACCELERATED TO CENTER • CENTER-HIGH;MARGINS-LOW
STENT RING PATTERN: • ALTERNATING TRAPEZOID CYCLES
MODULAR PATTERN: (2,2,2,2,2,2,2,2)
INTRA-MODULAR LINKS: (2-2,2-6,2-12,2-12,2-12,2-12,2-6,2-2)
INTRA-CONNECTING LINKS: (2,2,2,2,2,2,2,2) (7x2)
INTRA-CONNECTING LINK MODE: • LOOSELY SPIRAL
STENT LENGTH: • 20-22mm
END PIECE(S): • 2-2 MODULE: MODULE 2-2
INVENTION BY: • G. DAVID JANG, MD

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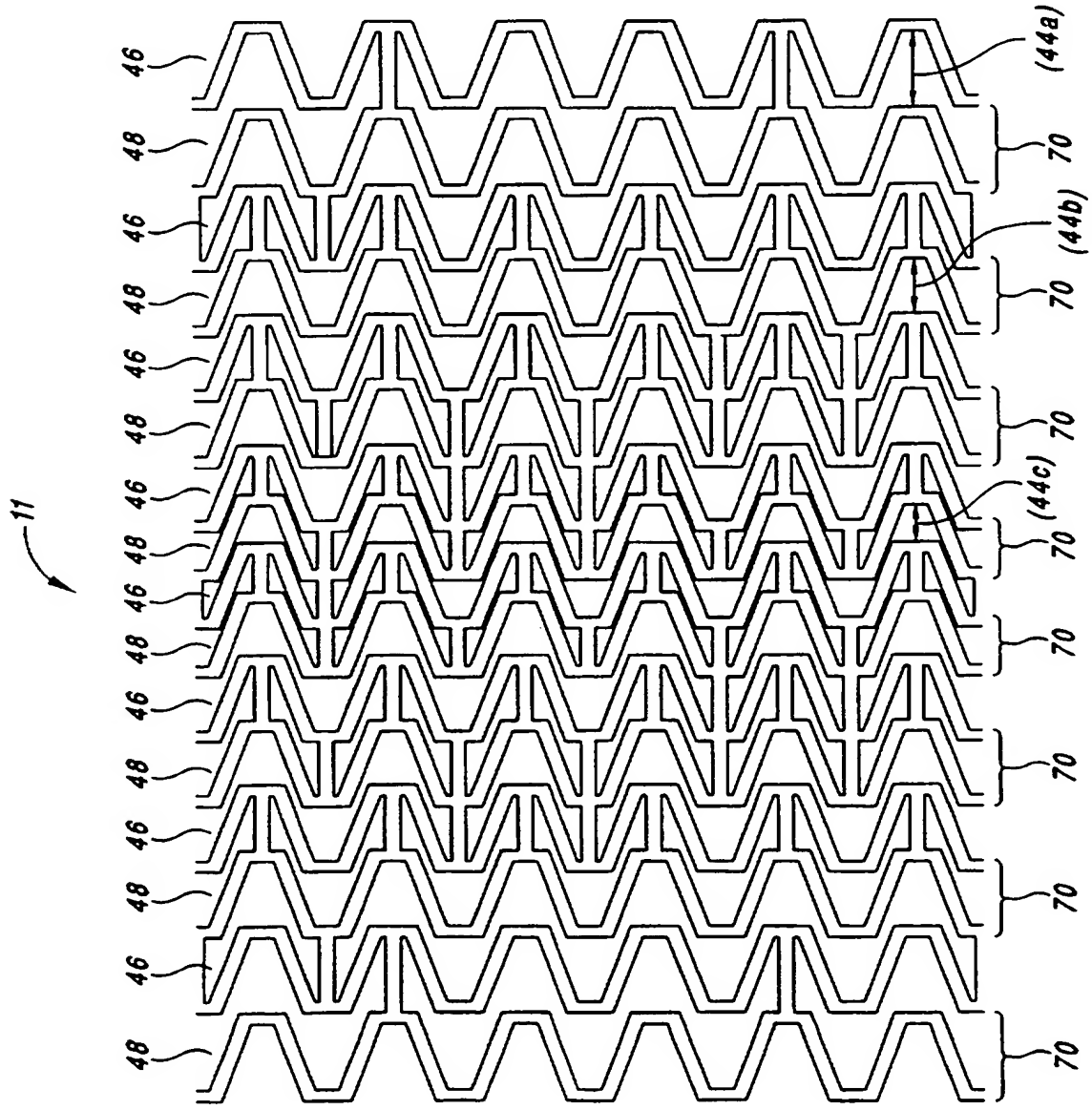

FIG. 21

RIGIDITY: • SYMMETRICALLY TAPERED FROM CENTER
FLEXIBILTY: • PROGRESIVE FROM CENTER
FRAME DENSITY: • ACCELERATED TO CENTER • CENTER-HIGH;MARGINS-LOW
STENT RING PATTERN: • ALTERNATING TRAPEZOID CYCLES
MODULAR PATTERN: (1,2,2,2,2,2,1)
INTRA-MODULAR LINKS: (2-6,2-12,2-12,2-12,2-12,2-6)
INTRA-CONNECTING LINKS: (2,2,2,2,2,2,2) (7x2)
INTRA-CONNECTING LINK MODE: • LOOSELY SPIRAL
STENT LENGTH: • 15-18mm
END PIECE(S): • 1xSINGLE: SINGLEx1
INVENTION BY: • G. DAVID JANG, MD

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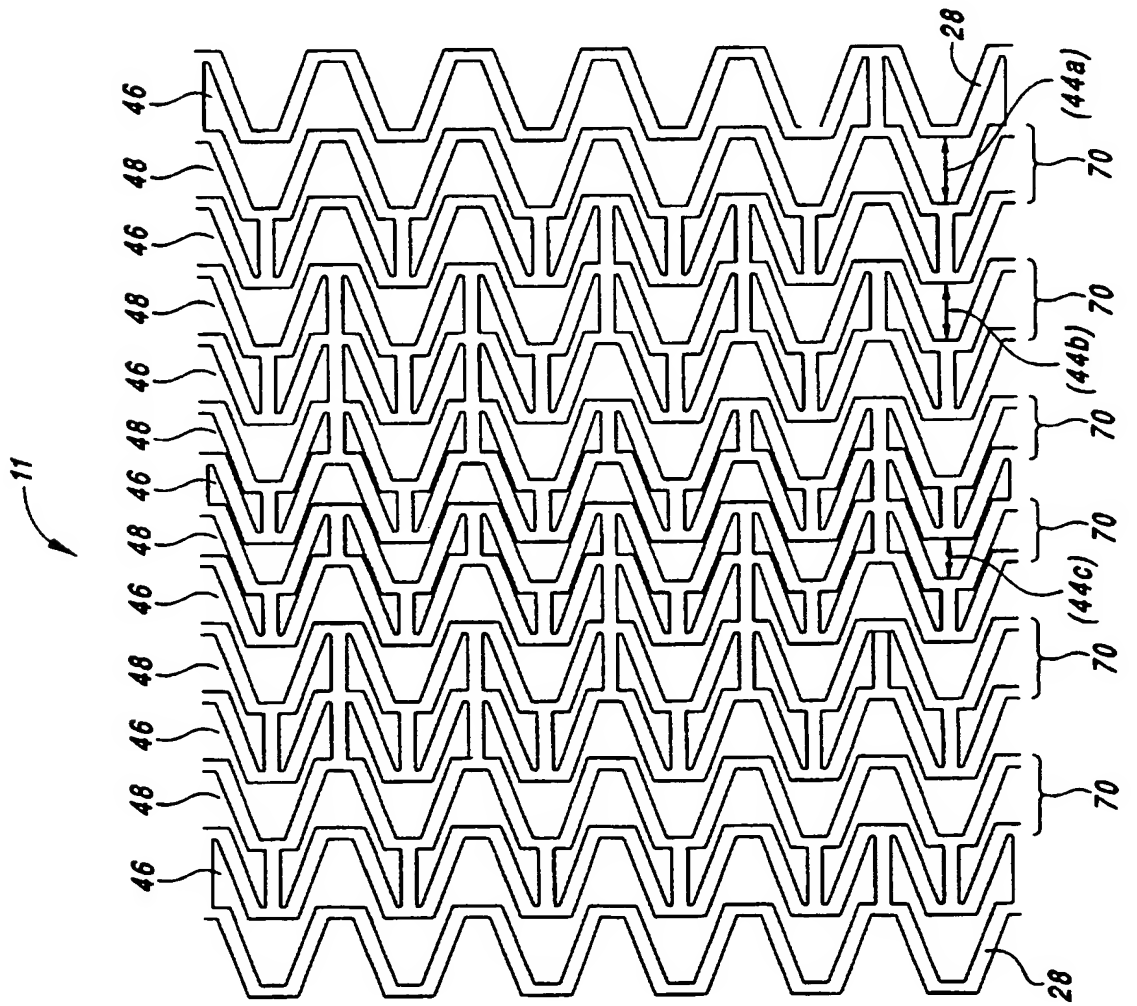

FIG. 22

RIGIDITY: • ASYMMETRICALLY TAPERED
FLEXIBILITY: • CENTER SHIFTED TO LEFT • PROGRESSIVE FLEX TO RIGHT
FRAME DENSITY: • ASYMMETRICAL ACCELERATION • HIGH DENSITY CENTER TO LEFT
STENT RING PATTERN: • ALTERNATING TRAPEZOID CYCLES
MODULAR PATTERN: (1,2,2,2,2,2,2,1,1)
INTRA-MODULAR LINKS: (2-6,2-12,2-12,2-12,2-12,2-12,2-6,2-2)
INTRA-CONNECTING LINKS: (2,2,2,2,2,2,2,2,2) (9x2)
INTRA-CONNECTING LINK MODE: • LOOSELY SPIRAL
STENT LENGTH: • 20-25mm
END PIECE(S): • 1xSINGLE: SINGLEx2
INVENTION BY: • G. DAVID JANG, MD

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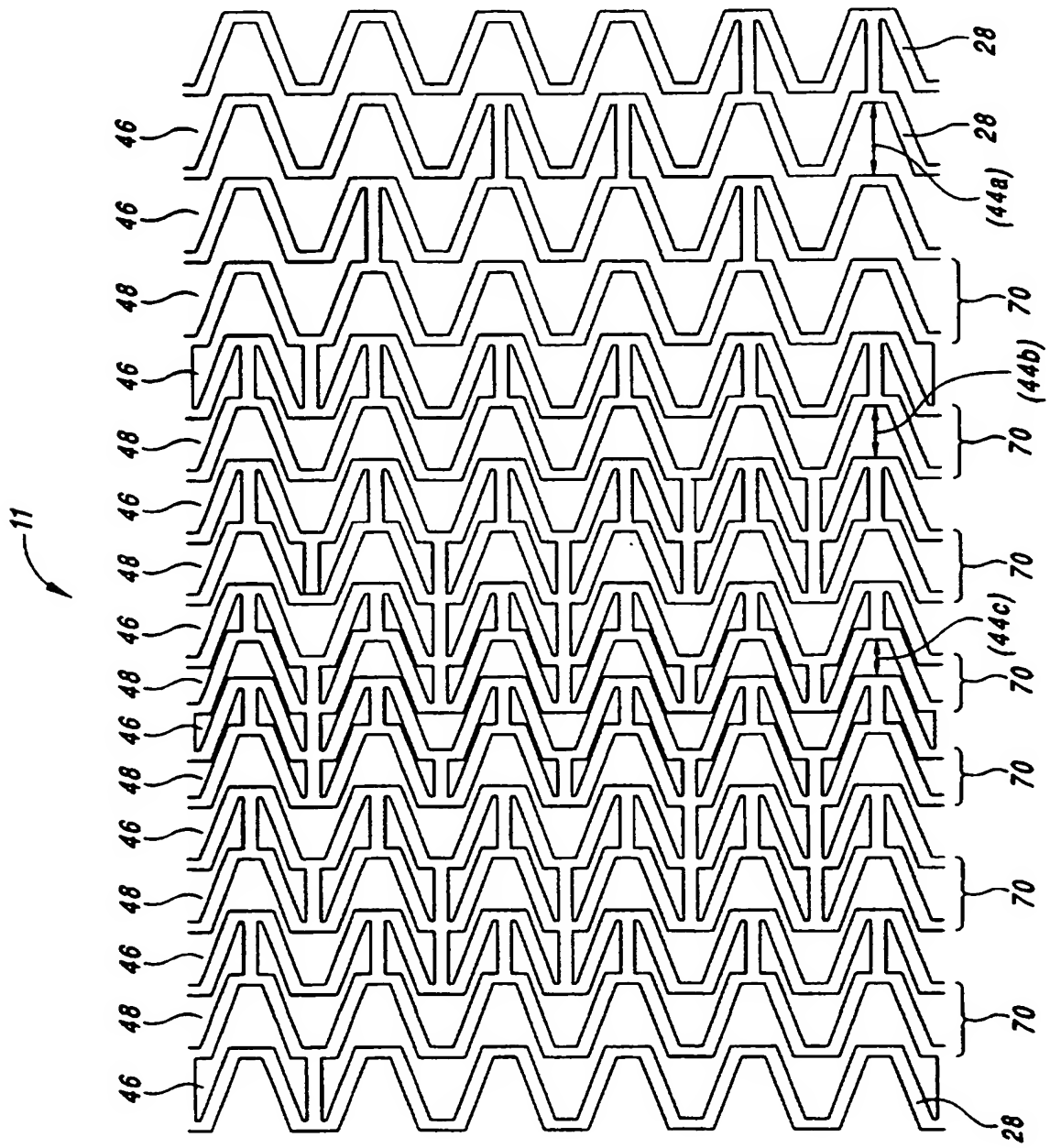

FIG. 23

RIGIDITY: • ASYMMETRICALLY TAPERED
FLEXIBILITY: • CENTER SHIFTED TO LEFT • PROGRESSIVE FLEX TO RIGHT
FRAME DENSITY: • ASYMMETRICAL ACCELERATION • HIGH DENSITY CENTER TO LEFT
STENT RING PATTERN: • ALTERNATING TRAPEZOID CYCLES
MODULAR PATTERN: (2,2,2,2,2,2,1,1)
INTRA-MODULAR LINKS: (2-6,2-12,2-12,2-12,2-12,2-12,2-6,2-2)
INTRA-CONNECTING LINKS: (2,2,2,2,2,2,2,2) (8x2)
INTRA-CONNECTING LINK MODE: • LOOSELY SPIRAL
STENT LENGTH: • 18-20mm
END PIECE(S): • 2-6 MODULE: SINGLEx2
INVENTION BY: • G. DAVID JANG, MD

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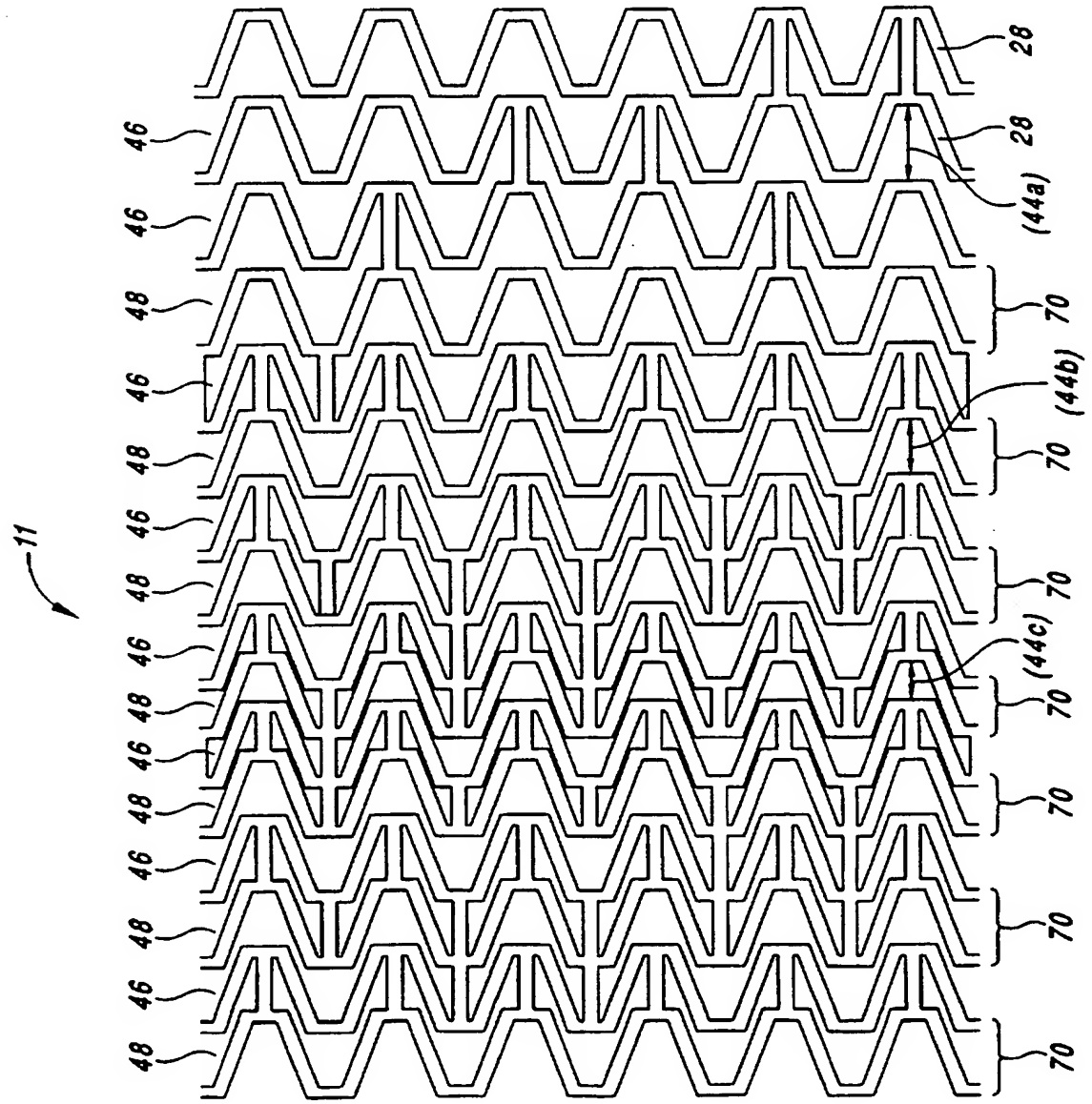

FIG. 24

RIGIDITY: • ASYMMETRICALLY TAPERED
FLEXIBILITY: • CENTER SHIFTED TO LEFT • PROGRESSIVE FLEX TO RIGHT
FRAME DENSITY: • ASYMMETRICAL ACCELERATION • HIGH DENSITY CENTER TO LEFT
STENT RING PATTERN: • ALTERNATING TRAPEZOID CYCLES
MODULAR PATTERN: (2,2,2,2,2,2,1,1)
INTRA-MODULAR LINKS: (2-12,2-12,2-12,2-12,2-6, 2-2,1,1)
INTRA-CONNECTING LINKS: (2,2,2,2,2,2,2) (8x2)
INTRA-CONNECTING LINK MODE: • LOOSELY SPIRAL
STENT LENGTH: • 15-18mm
END PIECE(S): • 2-12 MODULE: SINGLEx2
INVENTION BY: • G. DAVID JANG, MD

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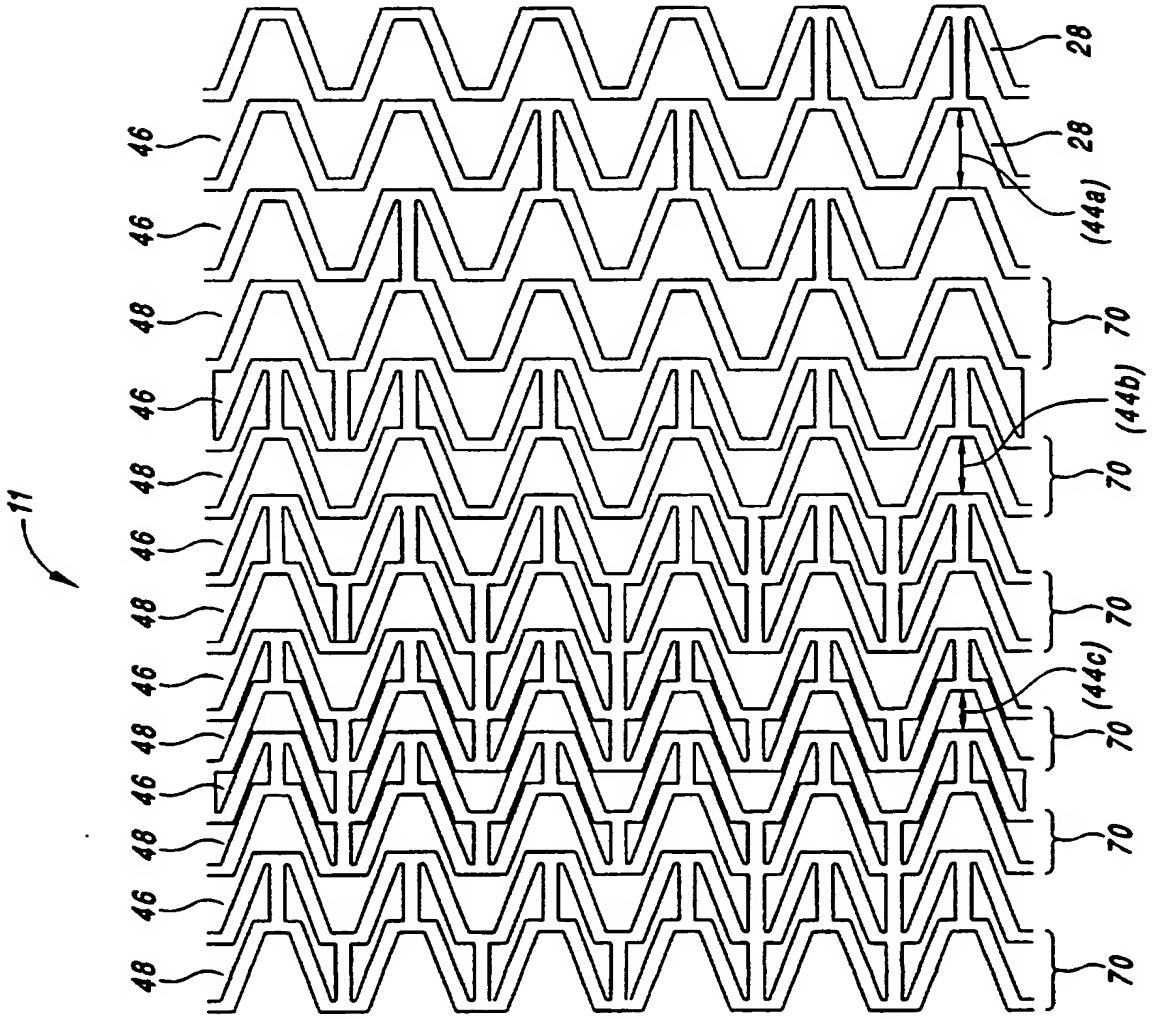

FIG. 25

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RIGIDITY: • ASYMMETRICALLY TAPERED
FLEXIBILTY: • CENTER SHIFTED TO LEFT • PROGRESSIVE FLEX TO RIGHT
FRAME DENSITY: • ASYMMETRICAL ACCELERATION • HIGH DENSITY CENTER TO LEFT
STENT RING PATTERN: • ALTERNATING TRAPEZOID CYCLES
MODULAR PATTERN: (2,2,2,2,2,2,2)
INTRA-MODULAR LINKS: (2-6,2-12,2-12,2-12,2-12,2-12,2-6,2-2)
INTRA-CONNECTING LINKS: (2,2,2,2,2,2,2) (7x2)
INTRA-CONNECTING LINK MODE: • LOOSELY SPIRAL
STENT LENGTH: • 12-15mm
END PIECE(S): • 2-6 MODULE: 2-2 MODULE
INVENTION BY: • G. DAVID JANG, MD

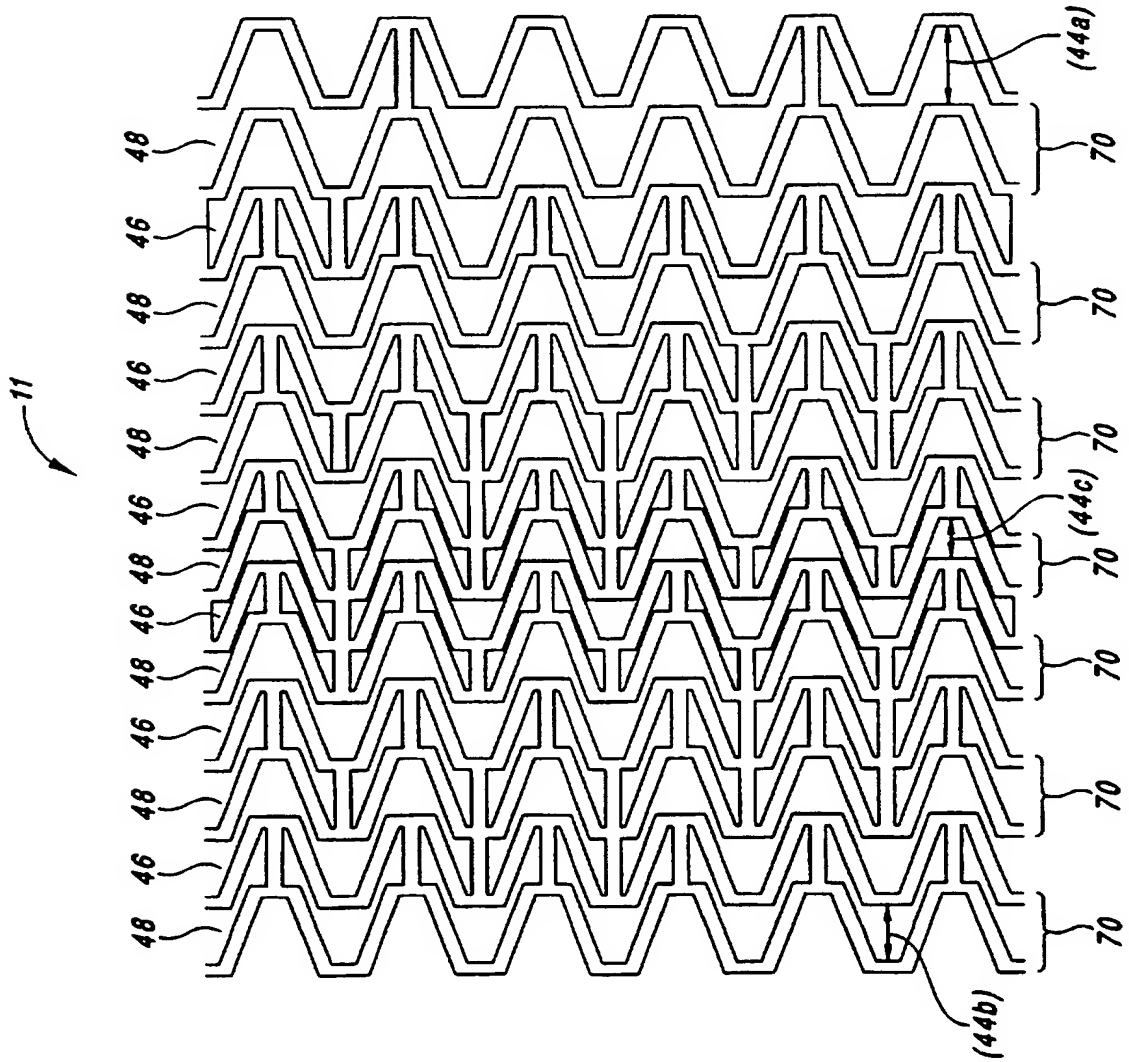

FIG. 26

INTERNATIONAL SEARCH REPORT

Inter nal Application No
PCT/US 97/00828

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP 0 540 290 A (ADVANCED CARDIOVASCULAR SYSTEMS) 5 May 1993 see column 6, line 34 - line 49; figures ---	1,4,5,9, 10
Y	WO 95 21592 A (MINTEC) 17 August 1995 see page 16, line 3 - line 16; figures ---	1,4,5,9, 10
A	EP 0 662 307 A (ADVANCED CARDIOVASCULAR SYSTEMS) 12 July 1995 see abstract; figures see column 8, line 4 - line 11 see page 10, line 19 - line 24 ---	1,3
A	WO 95 32757 A (NITINOL MEDICAL TECHNOLOGIES) 7 December 1995 see page 15, line 5 - line 20 ---	1,2,9,10
	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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Date of the actual completion of the international search	Date of mailing of the international search report
24 April 1997	15.05.97

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax (+ 31-70) 340-3016	Steenbakker, J

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INTERNATIONAL SEARCH REPORT

Inter nal Application No
PCT/US 97/00828

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 95 18585 A (MICROFIL INDUSTRIES) 13 July 1995 ---	
P,X	WO 96 14028 A (DIVYSIO) 17 May 1996 see page 12, line 17 - page 13, line 2; figure 2 -----	1,9

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INTERNATIONAL SEARCH REPORT

..nformation on patent family members

Inter ..nal Application No
PCT/US 97/00828

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